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PATENT

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First Named Inventor or Application Identifier: GEORGE MAMO and MICHELE SPINELLI
Title: MINIMALLY INVASIVE METHOD FOR IMPLANTING A SACRAL STIMULATION LEAD

CERTIFICATE UNDER 37 CFR SECTION 1 10 I hereby certify that this New Application Transmittal and the documents referred to as enclosed therein are being deposited with the United States Postal Service, in an envelope address "EXPRESS EL **084633248** US addressed to Box Patent Application, Commissioner of Patents and Trademarks, Washington, D C 20231, on this NOVEMBER 15, 2000

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We are transmitting the following:

X **Patent Application Transmittal**
X **Specification**
Total Pages: 27 (cover/title page 1 sheet; specification 16 sheets; claims 9 sheets; abstract 1 sheet)
X (informal) **Drawings**
Total Sheets: 25 (_ formal; X informal)
X **Combined Declaration and Power of Attorney:**
- X Newly executed
- _ Copy from prior application
- _ Deletion of inventor(s) -- signed statement attached deleting inventor(s) named in the prior application (37 CFR 1.63(d)(2) and 1.33(b)
- _ Incorporation by reference -- *The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied above is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference herein.*

X **Accompanying application parts:**
- _ Notification of filing a _ Continuation _ Divisional _ Continuation-in-Part
- X Assignment of the invention to Medtronic, Inc.
- X Assignment cover sheet
- X Information Disclosure Statement
- X PTO Form 1449
- X Copies of IDS citations
- _ Preliminary Amendment
- _ A copy of the Petition or Condition Petition for Extension of Time in the prior application
- X Return postcard

IF A CONTINUING APPLICATION:

_ Continuation _ Divisional _ Continuation-in-Part of prior application no. __.

_ Amend the specification by inserting before the first line the sentence: This application is a _ Continuation _ Divisional _ Continuation-in-Part of application number _ filed _.

_ Cancel in this application original claims _ of the prior application before calculating the filing fee. (At least one of the original independent claims must be retained for filing purposes.)

_ The prior application is assigned of record to Medtronic, Inc.

__ The Power of Attorney in the prior application is to: _.

_ This application claims the benefit of U.S. Provisional Application(s) Serial No. _filed _____.

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FEE CALCULATION

	No. Of Claims Filed	Claims Included in Base Fee	No. Of Extra Claims	Rate	Fee
Total Claims	57	20 =	37	x $ 18	$ 666.00
Independent Claims	8	3 =	5	x $80	$ 400.00
Multiple Dependent Claim(s)		0 =		+ $ 260	
Basic Filing Fee			0		$710.00
				TOTAL	**$1776.00**

X Charge Deposit Account No. 13-2546 the sum of $710.00 (Filing Fee) and $40.00 for Assignment recordation fee for a total of **$1,816.00.**

X The Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. 13-2546. A duplicate of this transmittal is enclosed.

15 NOV 00
Date

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PATENT
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APPLICATION FOR UNITED STATES LETTERS PATENT

for

MINIMALLY INVASIVE METHOD FOR IMPLANTING A SACRAL STIMULATION LEAD

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MINIMALLY INVASIVE METHOD FOR IMPLANTING A SACRAL STIMULATION LEAD

CROSS REFERENCE

This disclosure is related to the following copending application entitled "Minimally Invasive Surgical Techniques For Implanting Devices That Deliver Stimulation To The Nervous System" by inventors Gerber et al. (Application No. 09/489,544; filed January 31, 2000), which is not admitted as prior art with respect to the present disclosure by its mention in this cross reference section.

BACKGROUND OF THE INVENTION

This disclosure relates to a method for surgically implanting an electric neurostimulation lead in the human sacrum.

The medical device industry produces a wide variety of electronic and mechanical devices for treating patient medical conditions. Depending upon the medical condition, medical devices can be surgically implanted or connected externally to a patient receiving treatment. Clinicians use medical devices alone or in combination with drug therapies and surgery to treat patient medical conditions. For some medical conditions, medical devices provide the best, and sometimes the only, therapy to restore an individual to a more healthful condition and a fuller life. Conditions that medical devices can effectively treat include pelvic floor disorders.

Pelvic floor disorders adversely affect the health and quality of life of millions of people. Pelvic floor disorders include urinary control disorders such as urge incontinency, urge frequency, voiding efficiency, fecal control disorders, sexual dysfunction, and pelvic pain. Individuals with urinary control disorders often face debilitating challenges in their everyday

lives. These individuals can be preoccupied with trips to the bathroom, fears of embarrassment, and sleepless nights. Some suffers become so anxious that they become isolated and depressed. Pelvic floor disorders can be treated with a variety of therapeutic options such as behavior modification including biofeedback, pharmacological treatment, mechanical intervention such as self-catheterization, physical appliances such as diapers, and surgical intervention. Surgical treatments are the most invasive and are often considered after other therapies have proven ineffective.

One surgical technique to treat urinary control disorders is the implantable InterStim® therapy, available from Medtronic, Inc., which applies mild electrical stimulation to the sacral nerves in the lower region of the spine to influence behavior of structures such as the bladder, sphincter and pelvic floor muscles. Generally, implantation of InterStim therapy involves surgically implanting a stimulation lead near the sacral nerves. The stimulation lead is a very small, insulated electrical conductor with electrical stimulation contacts on the distal end placed near the sacral nerves and an electrical connector on the opposite proximal end of the lead. The lead electrical connector is typically connected to a small extension, and the extension is connected to a small neurostimulator that operates similar to a cardiac pacemaker by delivering occasional small electrical pulses that sometimes create a tingling sensation felt by the patient. The stimulation lead, lead extension, and neurostimulator are all implanted in the patient in a manner that is typically not perceptible by others. InterStim therapy can improve the condition of a pelvic floor disorder patient and allow the patient to lead a full life. Also, InterStim therapy is nondestructive and reversible.

Previous surgical methods to implant a neurostimulation lead in a patient's sacrum to treat pelvic floor disorders have been invasive by requiring a large sacral incision in a procedure

known as dissection. FIG. 1a (prior art) shows a sacral dissection. Dissection involves making a midline incision over the sacrum from a little below S4 up to S1 that in an adult ranges from about 7.62 cm (3.0 inches) to 12.7 cm (5.0 inches). After the incision is made, the fascia lateral to the midline is cleaned off and divided in the direction of the incision approximately one finger width lateral to the midline. Next, the paraspinal muscle fibers are split and sharply retracted. Once the muscle fibers are retracted, the sacral foramen is exposed while preserving the periosteum. Next, the desired foramen is located by observing anatomical landmarks and palpating for a marble-board-like depression. FIG. 1b (prior art) shows a foramen dissection. Once the desired foramen is located, another small incision is made over the desired foramen that is large enough to allow insertion of the stimulation lead. The stimulation lead is inserted through the incision. Surgically implanting the stimulation lead in this manner near the patient's sacral nerve can cause patient complications, create significant patient's recovery time, and create a significant expense to the healthcare system. An example of the previous surgical method to implant a neurostimulation lead is described in Medtronic, "InterStim® Therapy Sacral Nerve Stimulation For Urinary Control Therapy Reference Guide," Section 5 InterStim Device Implantation Procedure, pp. 51-52 (1999).

For the foregoing reasons, there is a need for a less invasive surgical method to implant a neurostimulation lead in a patient sacrum's to reduce patient surgical complications, reduce patient recovery time, and decrease surgical costs while maintaining the substantial patient benefit that implanting a stimulation lead for sacral neurostimulation can provide.

SUMMARY OF THE INVENTION

The minimally invasive method for sacral stimulation lead implantation in a patient begins by inserting a needle posterior to the sacrum through an entry point. The needle is guided

into a foramen along an insertion path to a desired location. The insertion path is dilated with a dilator to a diameter sufficient for inserting a stimulation lead. The needle is removed from the insertion path. The stimulation lead is inserted in the insertion path to the desired location. Finally, the dilator is removed from the insertion path. Additionally if the clinician desires to separately anchor the stimulation lead, an incision can be created through the entry point from an epidermis to a fascia layer. The stimulation lead is anchored to the fascia layer. Finally, the incision is closed. The minimally invasive method for sacral stimulation lead implantation can be practiced in a wide variety of embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1a shows a prior art sacral dissection;

FIG. 1b shows a prior art foramen dissection;

FIG. 1c shows an environment of a patient undergoing a sacral stimulation procedure;

FIG. 2 shows an embodiment of an implanted neurostimulator;

FIGS. 3a-3g show some surgical tools that can be used to perform the minimally invasive method;

FIG. 4 shows a flowchart of a first minimally invasive method embodiment;

FIG. 5a shows a flowchart of a second minimally invasive method embodiment;

FIG. 5b shows a needle being inserted into a foramen embodiment;

FIG. 5c shows a cross section view of FIG. 5b;

FIG. 5d shows the needle being used as a guide for a larger needle embodiment;

FIG. 5e shows removal of a stylet and insertion of a stimulation lead embodiment;

FIG. 5f shows another view of insertion of the stimulation lead embodiment;

FIG. 5g shows removal of the needle and insertion of an anchor embodiment;

FIG. 5h shows fixation of the anchor embodiment;

FIG. 5i shows another stimulation lead fixation embodiment;

FIG. 5j shows another view of the stimulation lead fixation embodiment shown in the FIG. 5i embodiment;

FIG. 5k shows an anchored stimulation lead that is tunneled for connection to a medical device;

FIG. 6a shows a flowchart of a third minimally invasive method embodiment;

FIG. 6b shows a patient having a needle inserted posterior to the patient sacrum embodiment;

FIG. 6c shows an anatomical drawing of the needle inserted as shown in the FIG. 6b embodiment;

FIG. 6d shows a patient having a guide wire inserted through the needle;

FIG. 6e shows an anatomical drawing of the guide wire inserted as shown in the FIG. 6d embodiment;

FIG. 6f shows a patient having a dilator placed over the guide wire embodiment;

FIG. 6g shows an anatomical drawing of the dilator placed over the guide wire as shown in the FIG. 6f embodiment;

FIG. 6h shows a patient having the dilator inserted into the sacrum embodiment;

FIG. 6i shows an anatomical drawing of the dilator inserted into the sacrum as shown in the FIG. 6h embodiment;

FIG. 6j shows preparation for inserting the stimulation lead into the dilator embodiment;

FIG. 6k shows inserting the stimulation lead into the dilator embodiment;

FIG. 6l shows removal of the dilator embodiment;

FIG. 6m shows creating an incision at the stimulation lead insertion site embodiment;

FIG. 6n shows marking the stimulation lead embodiment;

FIG. 6o shows an anatomical cross-section drawing of marking the stimulation lead embodiment;

FIG. 6p shows applying a lead anchor to the stimulation lead embodiment;

FIG. 6q shows tunneling the stimulation lead embodiment;

FIG. 6r shows fixation of the lead anchor to the lead body embodiment;

FIG. 6s shows fixation of the lead anchor to fascia of the patient embodiment;

FIG. 7a shows a flowchart of a fourth minimally invasive embodiment;

FIG. 7b shows an anatomical cross-section of creating an incision and inserting the needle embodiment;

FIG. 7c shows an anatomical cross-section of insertion of the guide embodiment;

FIG. 7d shows an anatomical cross-section of the guide in place after the needle has been removed embodiment;

FIG. 7e shows an anatomical cross-section of placement of the stimulation lead over the guide embodiment;

FIG. 7f shows an anatomical cross-section of fixing the stimulation lead to a patient's fascia and removal of the guide embodiment; and,

FIG. 7g shows an anatomical cross-section of closing the incision and tunneling the stimulation lead embodiment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1c shows an environmental view of a sterile area in which the minimally invasive method for implanting a sacral stimulation lead can be performed. The method can be performed in a wide variety of locations 20 that have a sterile field and common medical instruments such as an operating room, surgery center. The method and its many embodiments are typically performed by a urologist 22, but can be performed by many clinicians 22 trained in stimulation

lead implantation. The patient 24 is placed under local or general anesthesia. With local anesthesia, the method can potentially be performed in a clinician's 22 office for greater accessibility and reduced costs. A sacral stimulation lead can be implanted for a variety a purposes such as to treat pelvic floor disorders. Pelvic floor disorders include urinary control disorders, fecal control disorders, sexual dysfunction, and pelvic pain.

FIG. 2 shows an embodiment of an implanted neurostimulator 26 to stimulate sacral nerves 27 located near the sacrum 28. The sacral nerves are assessable through an entry point 29 along an insertion path 33 into a foramen 31 to reach a desired location 35. A neurostimulation system can include a stimulation lead 30, a lead anchor (FIG. 3g), a lead extension 32, a trial stimulator (not shown), an implantable neurostimulator 26, a physician programmer (not shown), and a patient programmer (not shown). The stimulation lead 30 has electrical contacts 34 positioned on the distal end to stimulate nerves and connectors (not shown) on the proximal end to connect to a lead extension or directly to the trial neurostimulator or implantable neurostimulator 26. The stimulation lead 30 can be a Medtronic Model 3886 quadrapolar lead without anchor having a diameter of approximately a 0.127 cm (0.050 inch) and designed to accept a stylet through the center of the stimulation lead 30 to assist in insertion. The lead anchor (FIG. 3f) fixes the stimulation lead 30 to prevent the stimulation lead 30 from migrating away from the position selected by the implanting clinician 22. The lead extension 32 connects between the stimulation lead 30 and the trial stimulator or implantable stimulator 26. The trial neurostimulator tests the effectiveness of stimulation to treat the patient's condition prior to implantation of an implantable neurostimulator 26.

The implantable neurostimulator 26 provides a programmable stimulation signal that is delivered to a desired location or target to stimulate selected nerves. The implantable

neurostimulator 26 is typically implanted in a subcutaneous pocket around the upper buttocks sometime after the stimulation lead 30 has been implanted and its effectiveness verified. The physician programmer is used by the clinician 22 to communicate with the implantable neurostimulator 26 to program the stimulation signal produced by the implantable neurostimulator. The patient programmer allows the patient to communicate with the implantable neurostimulator to control certain parameters of the stimulation signal typically selected by a clinician. With a pelvic floor disorder, a patient can typically control stimulation signal parameters such as voltage amplitude. Neurostimulation systems with the components discussed above are available from Medtronic, Inc. in Minneapolis, Minnesota.

FIGS. 3a-3g show some of the surgical instruments (not to scale) typically available to the implanting clinician to aid in implanting the stimulation lead 30. Local anesthetic is delivered to the patient typically with a syringe such as a Luer Slip Disposable 12cc syringe (not shown). The needle 36 is selected based upon the needs of the patient 24 typically ranging in size from an outer diameter of about 26 gauge to about 12 gauge such as the 20 gauge, thin wall, foramen needle 38 Models 041828 and 041829 available from Medtronic. The foramen needle 38 has a stylet 40, also known as an obturator, in the foramen needle 38 central opening and markings that measure 1.0 cm increments and a wider mark at 5.0 cm to aid in positioning needle depth. Additionally the foramen needle 38 tip and proximal portion adjacent to the hub are conductive, so a trial stimulator can be electrically connected to the hub. The trial stimulator stimulation signal will travel to the foramen needle 38 tip to evoke a response from the patient 24 to determine if the foremen needle 38 is properly position and whether the patient 24 will likely benefit from stimulation.

The dilators 42 can be metal or plastic dilators typically ranging in size from an outer diameter of about 5 French to about 14 French, such as an Angiocath® intravenous catheter placement unit available from Parke Davis & Company, selected based upon the size of stimulation lead 30 to be implanted. Multiple dilators 42 can be used typically in sequence from a smaller diameter to a larger diameter to achieve the desired dilation while controlling tissue trauma. The guide wire 44 is typically a thin biocompatible stainless steel wire with a diameter such as 0.076 cm (0.030 inch). Dilators 42 and guide wires 44 are available in cardiac pacing lead introducer kits such as Medtronic's Model 3208, Percutaneous Lead Introducer. The dilator 42 can be a metal or plastic dilator sized appropriately to pass the stimulation lead 30 such as an 8 French sized dilator. The neurostimulation lead anchor 46 is an implantable surgical anchor configured to fix to the stimulation lead 30 such as a suture anchor or a twist-lock anchor available in the Medtronic Model 3550-1 Boots and Anchors Accessory Kit or the silicone anchor included in the Medtronic Model 3886 Lead Electrode Kit. Additionally to assist the clinician 22 in guiding placement of the needle 36 and guide wire 44, the clinician 22 may use a fluoroscope or x-ray machine.

First Minimally Invasive Method Embodiment

FIG. 4 shows a flowchart of a first embodiment of the minimally invasive implantation method. FIG. 2 shows an embodiment of an implanted neurostimulator 26 to stimulate sacral nerves 27, and FIGS. 3a-3g show some surgical tools that can be used to perform the minimally invasive method. Prior to beginning the first method for minimally invasive method embodiment 48 for sacral electrical stimulation lead 30 implantation in a patient 24, the following preparatory actions are typically taken. A local anesthetic is typically applied to anesthetize the area where the stimulation lead 30 will be implanted such as posterior to the

sacrum 28. Since embodiments of the method permit use of a local anesthetic, patients 24 can be treated on an outpatient basis to greatly reduces costs over inpatient care and reduce recovery time. This significant cost reduction also makes sacral stimulation lead 30 implantation and its many beneficial therapies available to more patients 24 because healthcare payers are more likely to cover procedure costs. Also by using local anesthesia, the implanting clinician 22 can use the patient's 24 conscious sensory response to stimuli such as trial stimulation to aid in placing the stimulation lead 30. By using the patient's 24 conscious sensory response during stimulation lead 30 placement, the stimulation lead 30 can be more accurately placed reducing the potential for an ineffective therapy and reducing the potential for patient 24 injury caused by a misplaced lead 30. Other forms of anesthesia can also be used such as general anesthesia. Once the patient 24 has been anesthetized, the first method embodiment 48 can begin.

A needle 36 is inserted 50 posterior to the sacrum 28 through an entry point 29 typically created with the needle 36. The needle 36 can take a variety of forms such as a needle without a hub (cannula), a solid rod with a sharp tip, a needle with a hub that can be removed for example by a cutting tool, or a foramen needle 38 modified to have an extended length and a hub that can be removed with a cutting tool. The entry point 29 is typically a percutaneous entry created when the needle 36 is inserted. The needle 36 is hand guided 52 into the foramen 31 along an insertion path 33 to a desired location 35. The foramen's 31 approximate location can be found using anatomical landmarks, fluoroscopy, or x-rays. When guiding 52 the needle 36, the position of the needle 36 can be sensed by a variety of means such as by applying an electrical signal to the needle 36 to evoke a patient 24 response such as a motor or sensory response. Once the needle 36 is in position, the needle 36 can remain in the position to serve as a guide for the dilator 42, or in the alternative a guide wire 44 can be inserted through the needle 36. When the

needle 36 is used as a guide for the dilator 42, the needle hub 45 typically must be removed before the dilator 42 can be guided over the needle 36. Alternatively, a guide wire 44 can be used as the guide for the dilator 42. The guide wire 44 can be a flexible guide wire, a stiff guide wire, or a stylet. Once the guide wire 44 is in position, the needle 36 can be removed, and the guide wire 44 can serve as a guide for the dilator 42.

The insertion path 33 is dilated 54 with a dilator 42 to a diameter sufficient for inserting a stimulation lead 30. The needle 36 is removed 56 from the insertion path 33, or alternatively the guide wire 44 is removed 56 from the insertion path 33. When removing 56 the needle 36 from the insertion path 33, care should be taken to avoid displacing the dilator 42. The stimulation lead 30 is inserted 58 to the desired location 35. Since the chronic stimulation lead 30 is being inserted 58 directly without the requirement for a separate test stimulation lead (not shown), such as a Medtronic Test Simulation Lead Model 3057, the chronic stimulation lead 30 can be placed without positioning repeatability variation. Also, there is a greater correlation between acute test stimulation and chronic therapy stimulation because the same lead 30 is performing both test stimulation and therapy stimulation. The desired location 35 can be any area of the sacrum 28 intended to achieve a therapeutic effect such as into the foremen 31. One way to verify the stimulation lead's 30 position is to apply an electrical signal to the stimulation lead 30 to evoke a patient 24 motor or sensory response. Other ways to verify the stimulation lead's 30 position include imaging techniques such as fluoroscopy and x-ray. When inserting 58 the implantable stimulation lead 30, the lead 30 is advanced through the dilator 42 to the desired location 35 for stimulation. The dilator 42 is removed 60 from the insertion path 33. When removing 60 the dilator 42 from the insertion path 33, care should be taken to avoid displacing the stimulation lead 30. Additionally, stimulation lead 30 position should be re-verified by one of the previously

discussed techniques. Once the dilator 42 is removed, the clinician 22 may decide that the lead 30 does not need to be fixed because the patient's 24 physiology itself adequately stabilizes the lead 30. When the stimulation lead 30 is not separately fixed, patient 24 tissue disruption is minimized which provides for faster patient 24 recovery and potentially less stimulation lead 30 migration caused by disrupted tissue changes. If the clinician 22 does not wish to separately fix the stimulation lead 30, the first method embodiment 48 is completed. Optionally, the clinician 22 can separately fix the stimulation lead 30 by creating an incision 62, anchoring the lead 64, and closing the incision 66.

FIG. 5h shows an embodiment for separately fixing the stimulation lead. To separately fix the stimulation lead 30, an incision 68 through the entry point 29 is created from an epidermis 70 to a fascia layer 72 such as the lumbosacral fascia layer. This incision 68 can also be created at a later point in the method embodiment 48 without adversely affecting the method. The stimulation lead 30 is anchored 64 to the fascia layer 72. When anchoring 64 the stimulation lead 64 care is again should be taken to avoid displacing the stimulation lead 30. Finally, the incision 68 created for the anchor is closed 66. Since the first method embodiment 48 disrupts less tissue than the prior art method, patient 24 tissue disruption is minimized which provides for faster patient recovery and potentially less stimulation lead 30 migration caused by disrupted tissue changes.

A portion of the first minimally invasive method embodiment 48 can also be used simply for stimulation lead 30 placement for acute test stimulation rather than implantation. For stimulation lead 30 placement, typically the same procedure is used as for implantation through removing the dilator 60 from the insertion path 33. Once the dilator 42 is removed, stimulation lead 30 placement is validated to ensure the stimulation lead 30 is in the desired location 35.

Second Minimally Invasive Method Embodiment

FIG. 5a shows a flowchart of a second minimally invasive implantation method embodiment 74, and FIGS 5b-5k show various implementation element embodiments. The second minimally invasive method embodiment 74 is similar to the first minimally invasive method embodiment 48 with the exception that in the second method embodiment 74 includes an incision for anchoring that is created 62 after the needle has been guided 52 to a desired location 35 that is optional in the first method embodiment 48. By making the incision 62 earlier than optionally performed in the first minimally invasive method 48, the stimulation lead 30 can be more easily anchored 64 to a fascial layer 72 such as the lumbosacral fascia layer closer to the stimulation lead 30 distal end.

A portion of the second minimally invasive method embodiment 74 can also be used simply for stimulation lead 30 placement for acute test stimulation rather than implantation. For stimulation lead 30 placement, typically the same procedure is used as for implantation through removing the dilator 60 from the insertion path 33. Once the dilator is removed 60, stimulation lead 30 placement is validated to ensure the stimulation lead 30 is in the desired location 35.

Third Minimally Invasive Method Embodiment

FIG. 6a shows a flowchart of a third minimally invasive implantation method embodiment 76, and FIGS. 6b-6o show various implementation element embodiments. The third minimally invasive method embodiment 76 is similar to the first minimally invasive method embodiment 48 with the exception that a guide wire 44, stylet, or long needle is inserted 78 to guide the dilator 42 and the guide wire 44 is removed 80 after dilation has been completed. More specifically, after the needle 36 has been guided 52 into the foramen along an insertion path 33 to a desired location 35, a guide wire 44 is inserted into the needle 36 to the desired

location 35. Once the guide wire 44 is in place, the needle 36 is removed 56 while retaining the guide wire 44 at the desired location 35. The dilator 42 is placed over the guide wire 44 along the insertion path 33 to dilate 54 the insertion path 33 to a diameter sufficient for inserting 58 a stimulation lead 30. Once the dilator 42 is in place, the guide wire 44 is removed 80 from the dilator 42. After the stimulation lead 30 is in the desired location 35, the dilator 42 is removed 60. With the third minimally invasive method 76, once the dilator 42 is removed 60, the additional steps of creating an incision 62, anchoring the lead 64, and closing the incision 66 are optional. Once the dilator 42 is removed 60, the clinician 22 may decide that the stimulation lead 30 does not need to be fixed because the patient's 24 physiology itself adequately stabilizes the stimulation lead 30. If the clinician 22 determines the patient 24 requires the stimulation lead 30 fixation, then the clinician 22 would perform the elements of creating an incision 62, anchoring the lead 64, and closing the incision 66 as discussed previously.

A portion of the third minimally invasive method embodiment 76 can also be used simply for stimulation lead 30 placement for acute test stimulation rather than implantation. For stimulation lead 30 placement, typically the same procedure is used as for implantation through removing 60 the dilator 42 from the insertion path. Once the dilator 42 is removed 60, stimulation lead 30 placement is validated to ensure the stimulation lead 30 is in the desired location 35.

Fourth Minimally Invasive Method Embodiment

FIG. 7a shows a flowchart of a fourth minimally invasive implantation method embodiment 82, and FIGS. 7b-7g show various implementation element embodiments. The fourth minimally invasive method embodiment 82 is similar to the second minimally invasive method embodiment 74 with the exception that a guide wire 44 or stylet is inserted 78 to guide

the stimulation lead 30 and the stimulation lead 30 functions as the dilator 42, so a separate dilator 42 is not used. More specifically, after the incision 68 is created 62, a guide wire 44 is inserted 78 into the needle. Once the guide wire 44 is in the desired location 35, the needle 36 is removed 56 from the insertion path 33. In one embodiment, the stimulation lead 30 is configured with a centrally located stylet lumen and a pointed tip, so the stimulation lead 30 can serve as the dilator 42. The stimulation lead 30 is inserted over the guide wire 44 to the desired location 35. In another embodiment, the stimulation lead 30 is configured with a stylet lumen and also a pointed tip, so the stimulation lead 30 can serve as the dilator 42. The stimulation lead 30 stylet lumen is inserted 58 over the guide wire 44 and the stimulation lead 30 is advanced to the desired location 35. After the stimulation lead 30 is in the desired location 35, the guide wire 44 is removed 80 from the stimulation lead 30. Then the stimulation lead 30 is anchored 64 and the incision 68 is closed 66 similar to the second minimally invasive method embodiment 74.

A portion of the forth minimally invasive method embodiment 82 can also be used simply for stimulation lead 30 placement for acute test stimulation rather than implantation. For stimulation lead 30 placement, typically the same procedure is used as for implantation through removing 80 the guide wire 44 from the stimulation lead 30. Once the guide wire 44 is removed, stimulation lead 30 placement is validated to ensure the stimulation lead 30 is in the desired location 35.

Thus, embodiments of a minimally invasive sacral lead implantation method 48 are disclosed with many benefits. Embodiments of the method can reduce patient surgical complications, reduce patient recovery time, and reduce healthcare costs. One skilled in the art will appreciate that the present invention can be practiced with embodiments other than those

disclosed. The disclosed embodiments are presented for purposes of illustration and not limitation, and the present invention is limited only by the claims that follow.

ABSTRACT OF THE DISCLOSURE

Method embodiments to implant a stimulation lead in a patient's sacrum to deliver neurostimulation therapy can reduce patient surgical complications, reduce patient recovery time, and reduce healthcare costs. A method embodiment begins by inserting a needle posterior to the sacrum through an entry point. The needle is guided into a foramen along an insertion path to a desired location. The insertion path is dilated with a dilator to a diameter sufficient for inserting a stimulation lead. The needle is removed from the insertion path. The stimulation lead is inserted to the desired location. The dilator is removed from the insertion path. Additionally if the clinician desires to separately anchor the stimulation lead, an incision is created through the entry point from an epidermis to a fascia layer. The stimulation lead is anchored to the fascia layer. After the stimulation lead has been anchored, the incision can be closed, or the stimulation lead proximal end can be tunneled to where an implantable neurostimulator is located and then the incision can be closed. A implanted sacral stimulation lead can be connected to the neurostimulator to delivery therapies to treat pelvic floor disorders such as urinary control disorders, fecal control disorders, sexual dysfunction, and pelvic pain.

What is claimed is:

1. A method for minimally invasive sacral stimulation lead implantation in a patient, comprising:

inserting a needle posterior to the sacrum through an entry point;

guiding the needle into a foramen along an insertion path to a desired location;

dilating the insertion path with a dilator to a diameter sufficient for inserting a stimulation lead;

removing the needle from the insertion path;

inserting the stimulation lead to the desired location; and,

removing the dilator from the insertion path.

2. The method as in claim 1 further comprising,

creating an incision through the entry point from an epidermis to a fascia layer;

anchoring the stimulation lead to the fascia layer; and,

closing the incision.

3. The method as in claim 1 further comprising applying anesthetic to the patient.

4. The method as in claim 3 wherein the anesthetic is selected from the group consisting of local anesthetic, and general anesthetic.

5. The method as in claim 1 further comprising sensing a needle position in the patient by applying an electrical signal to the needle to evoke a patient response related to the needle position.

6. The method as in claim 1 further comprising inserting a guide wire through the needle to the desired location.

7. The method as in claim 1 wherein the stimulation lead is inserted into a foramen.

8. The method as in claim 1 wherein the stimulation lead is implanted to treat pelvic floor disorders.

9. The method as in claim 8 wherein the pelvic floor disorder are selected from the group consisting of urinary control disorders, fecal control disorders, sexual dysfunction, and pelvic pain.

10. The method as in claim 1 wherein the needle is selected from the group consisting of a needle without a hub, a needle with a hub, a solid rod with a sharp tip, and a foramen needle modified to have an extended length.

11. The method as in claim 1 wherein the needle size is in the range from about 26 gauge to about 12 gauge.

12. The method as in claim 1 wherein the dilator size is in the range from about 5 French to about 12 French.

13. The method as in claim 1 wherein anchoring is accomplished with an anchor selected from the group consisting of a suture anchor and a twist-lock suture anchor.

14. A method for minimally invasive sacral stimulation lead placement in a patient, comprising:

inserting a needle posterior to the sacrum through an entry point;

guiding the needle into a foramen along an insertion path to a desired location;

dilating the insertion path with a dilator to a diameter sufficient for inserting a stimulation lead;

removing the needle from the insertion path;

inserting the stimulation lead to the desired location;

removing the dilator from the insertion path; and,

validating that the stimulation lead is placed in the desired position.

15. The method as in claim 14 further comprising sensing a needle position in the patient by applying an electrical signal to the needle to evoke a patient response related to the needle position.

16. The method as in claim 14 wherein the stimulation lead is inserted into a foramen.

17. A method for minimally invasive sacral stimulation lead implantation in a patient, comprising:

inserting a needle posterior to the sacrum through an entry point;

guiding the needle into a foramen along an insertion path to a desired location;

creating an incision through the entry point from an epidermis to a fascia layer;

dilating the insertion path with a dilator using the needle as a guide to a diameter sufficient for inserting a stimulation lead;

removing the needle from the insertion path;

inserting the stimulation lead to the desired location;

removing the dilator from the insertion path;

anchoring the stimulation lead to the fascia layer; and,

closing the incision.

18. The method as in claim 17 further comprising applying a local anesthetic posterior to the sacrum.

19. The method as in claim 17 further comprising sensing a needle position in the patient by applying an electrical signal to the needle to evoke a patient response related to the needle position.

20. The method as in claim 17 further comprising inserting a guide wire through the needle to the desired location.

21. The method as in claim 17 wherein the stimulation lead is inserted into a foramen.

22. The method as in claim 17 wherein the stimulation lead is implanted to treat pelvic floor disorders.

23. The method as in claim 22 wherein the pelvic floor disorder are selected from the group consisting of urinary control disorders, fecal control disorders, sexual dysfunction, and pelvic pain.

24. The method as in claim 17 wherein the needle size is in the range from about 26 gauge to about 12 gauge.

25. The method as in claim 17 wherein the dilator size is in the range from about 5 French to about 12 French.

26. The method as in claim 17 wherein anchoring is accomplished with an anchor selected from the group consisting of a suture anchor and a twist-lock suture anchor.

27. A method for minimally invasive sacral stimulation lead placement in a patient, comprising:

inserting a needle posterior to the sacrum through an entry point;

guiding the needle into a foramen along an insertion path to a desired location;

creating an incision through the entry point from an epidermis to a fascia layer;

dilating the insertion path with a dilator using the needle as a guide to a diameter sufficient for inserting a stimulation lead;

removing the needle from the insertion path;

inserting the stimulation lead to the desired location;

removing the dilator from the insertion path; and,

validating that the stimulation lead is placed in the desired position.

28. The method as in claim 27 further comprising sensing a needle position in the patient by applying an electrical signal to the needle to evoke a patient response related to the needle position.

29. The method as in claim 27 wherein the stimulation lead is inserted into a foramen.

30. A method for minimally invasive sacral stimulation lead implantation in a patient, comprising:

inserting a needle posterior to the sacrum through an entry point;

guiding the needle into a foramen along a insertion path to a desired location;

inserting a guide wire into the needle to the desired location;

removing the needle while retaining the guide wire at the desired location;

dilating the insertion path with a dilator placed over the guide wire along the insertion path to a diameter sufficient for inserting a stimulation lead;

removing the guide wire from the dilator;

inserting the stimulation lead through the dilator to the desired location; and,

removing the dilator from the insertion path.

31. The method as in claim 30 further comprising,

creating an incision through the entry point from an epidermis to a fascia layer;

anchoring the stimulation lead to the fascia layer; and,

closing the incision.

32. The method as in claim 30 further comprising applying anesthetic to the patient.

33. The method as in claim 32 wherein the anesthetic is selected from the group consisting of local anesthetic, and general anesthetic.

34. The method as in claim 30 further comprising sensing a needle position in the patient by applying an electrical signal to the needle to evoke a patient response related to the needle position.

35. The method as in claim 30 further comprising inserting a guide wire through the needle to the desired location.

36. The method as in claim 30 wherein the stimulation lead is inserted into a foramen.

37. The method as in claim 30 wherein the stimulation lead is implanted to treat pelvic floor disorders.

38. The method as in claim 37 wherein the pelvic floor disorder are selected from the group consisting of urinary control disorders, fecal control disorders, sexual dysfunction, and pelvic pain.

39. The method as in claim 30 wherein the needle size is in the range from about 26 gauge to about 12 gauge.

40. The method as in claim 30 wherein the dilator size is in the range from about 5 French to about 12 French.

41. The method as in claim 30 wherein anchoring is accomplished with an anchor selected from the group consisting of a suture anchor and a twist-lock suture anchor.

42. A method for minimally invasive sacral stimulation lead placement in a patient, comprising:

inserting a needle posterior to the sacrum through an entry point;

guiding the needle into a foramen to along an insertion path to a desired location;

inserting a guide wire into the needle to the desired location;

removing the needle while retaining the guide wire at the desired location;

dilating the insertion path with a dilator placed over the guide wire along the insertion path to a diameter sufficient for inserting a stimulation lead;

removing the guide wire from the dilator;

inserting the stimulation lead through the dilator to the desired location; and,

removing the dilator from the insertion path.

43. The method as in claim 42 further comprising validating that the electrical stimulation lead is placed in the desired position.

44. The method as in claim 42 further comprising sensing a needle position in the patient by applying an electrical signal to the needle to evoke a patient response related to the needle position.

45. The method as in claim 42 wherein the stimulation lead is inserted into a foramen.

46. A method for minimally invasive sacral stimulation lead implantation in a patient, comprising:

inserting a needle posterior to the sacrum through an entry point;

guiding the needle into a foramen to along an insertion path to a desired location;

creating an incision through the entry point from an epidermis to a fascia layer;

inserting a guide wire into the needle;

removing the needle from the insertion path;

inserting the stimulation lead over the guide wire to the desired location;

removing the guide wire from the stimulation lead;

anchoring the stimulation lead to the fascia layer; and,

closing the incision.

47. The method as in claim 46 further comprising applying a local anesthetic posterior to the sacrum.

48. The method as in claim 46 further comprising sensing a needle position in the patient by applying an electrical signal to the needle to evoke a patient response related to the needle position.

49. The method as in claim 46 wherein the stimulation lead is inserted into a foramen.

50. The method as in claim 46 wherein the stimulation lead is implanted to treat pelvic floor disorders.

51. The method as in claim 50 wherein the pelvic floor disorder are selected from the group consisting of urinary control disorders, fecal control disorders, sexual dysfunction, and pelvic pain.

52. The method as in claim 46 wherein the needle size is in the range from about 26 gauge to about 12 gauge.

53. The method as in claim 46 wherein the dilator size is in the range from about 5 French to about 12 French.

54. The method as in claim 46 wherein anchoring is accomplished with an anchor selected from the group consisting of a suture anchor and a twist-lock suture anchor.

55. A method for minimally invasive sacral stimulation lead placement in a patient, comprising:

inserting a needle posterior to the sacrum through an entry point;

guiding the needle into a foramen along an insertion path to a desired location;

creating an incision through the entry point from an epidermis to a fascia layer;

inserting a guide wire into the needle;

removing the needle from the insertion path;

inserting the stimulation lead over the guide wire to the desired location;

removing the guide wire from the stimulation lead; and,

validating that the stimulation lead is placed in the desired location.

56. The method as in claim 55 further comprising sensing a needle position in the patient by applying an electrical signal to the needle to evoke a patient response related to the needle position.

57. The method as in claim 55 wherein the stimulation lead is inserted into a foramen.

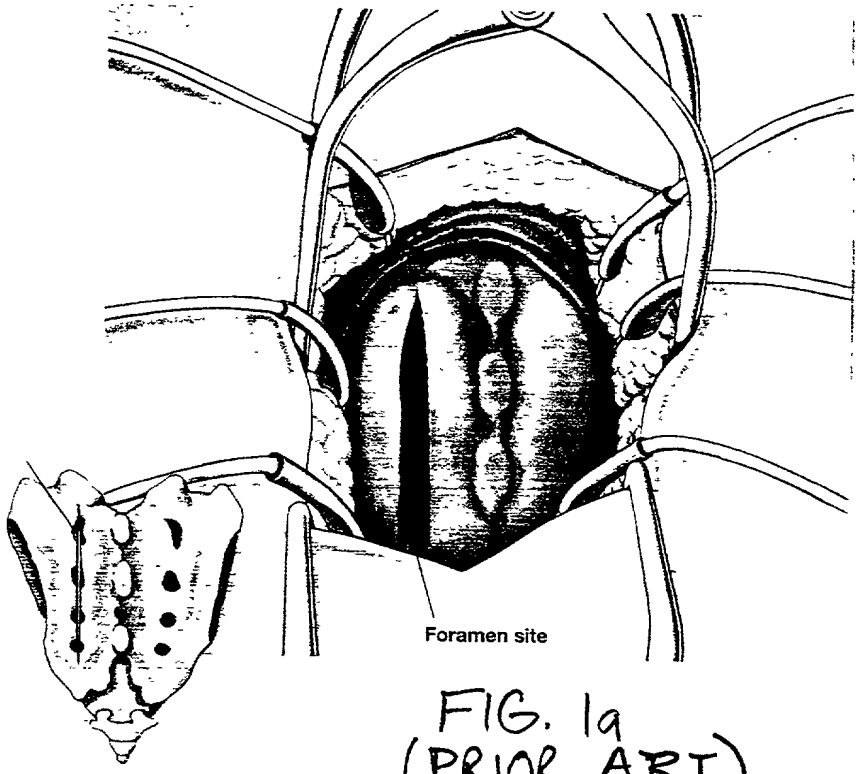


FIG. 1a
(PRIOR ART)

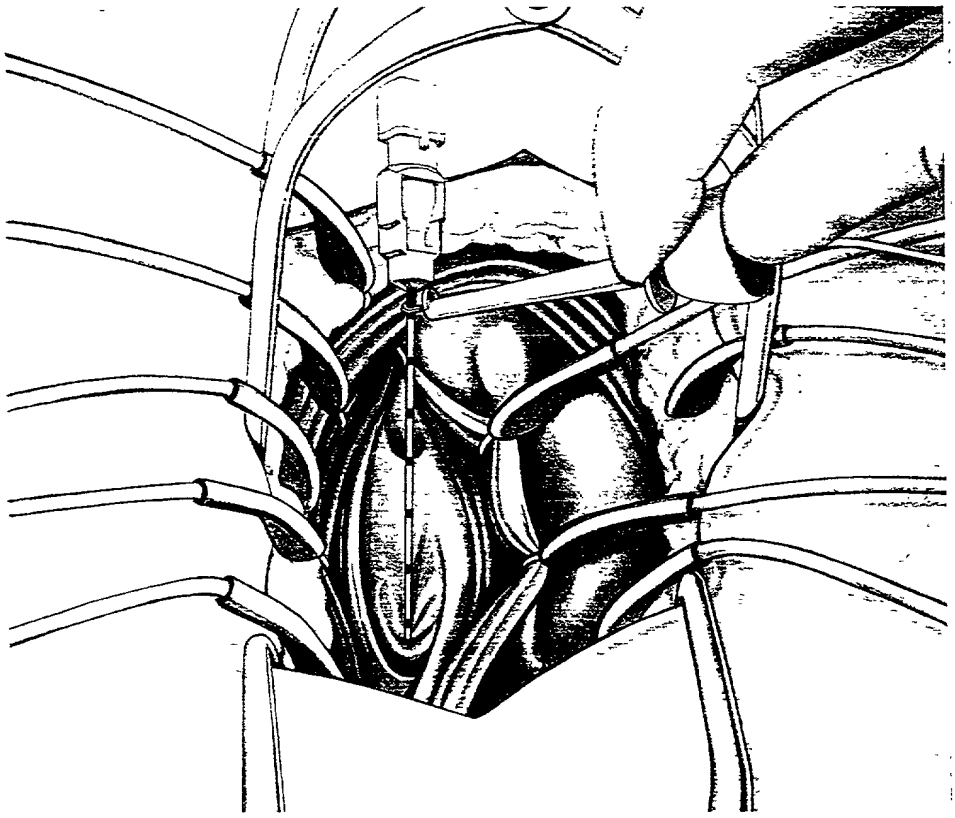


FIG. 1b
(PRIOR ART)

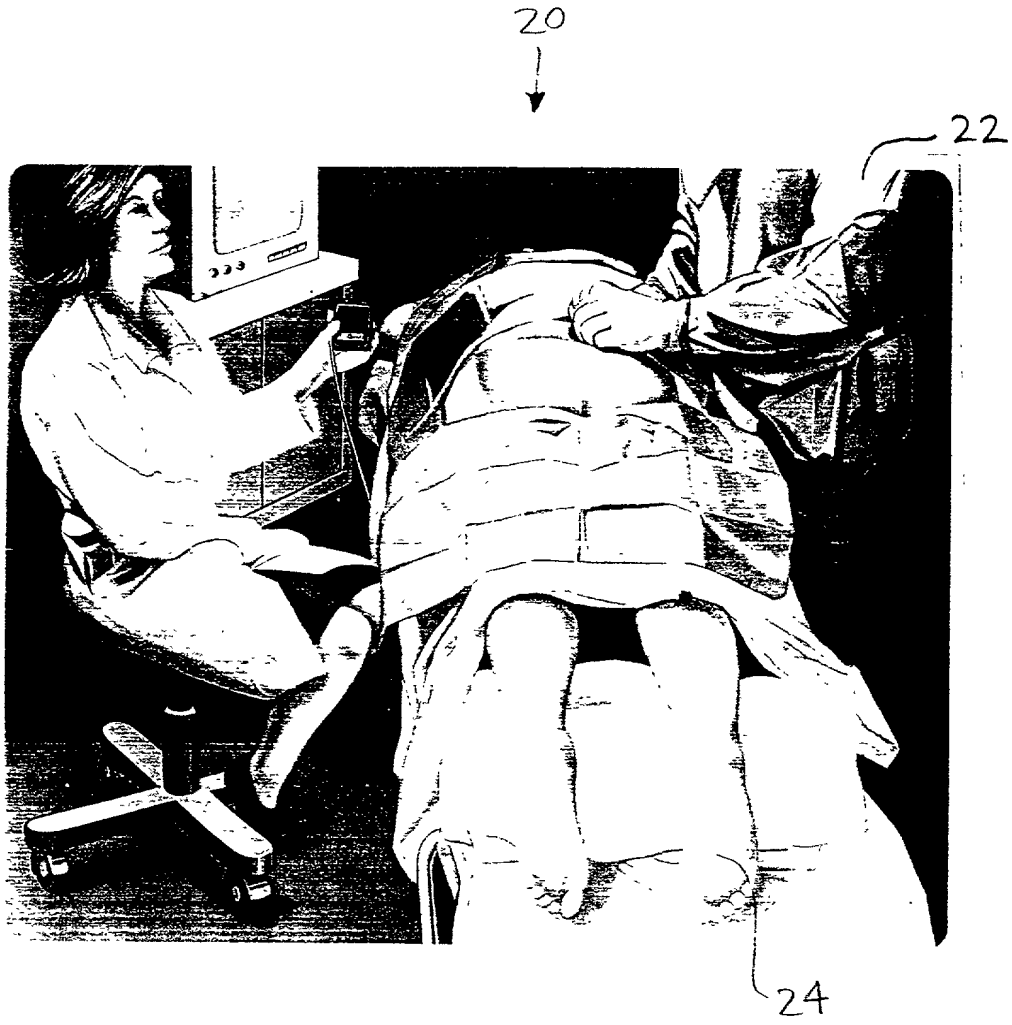
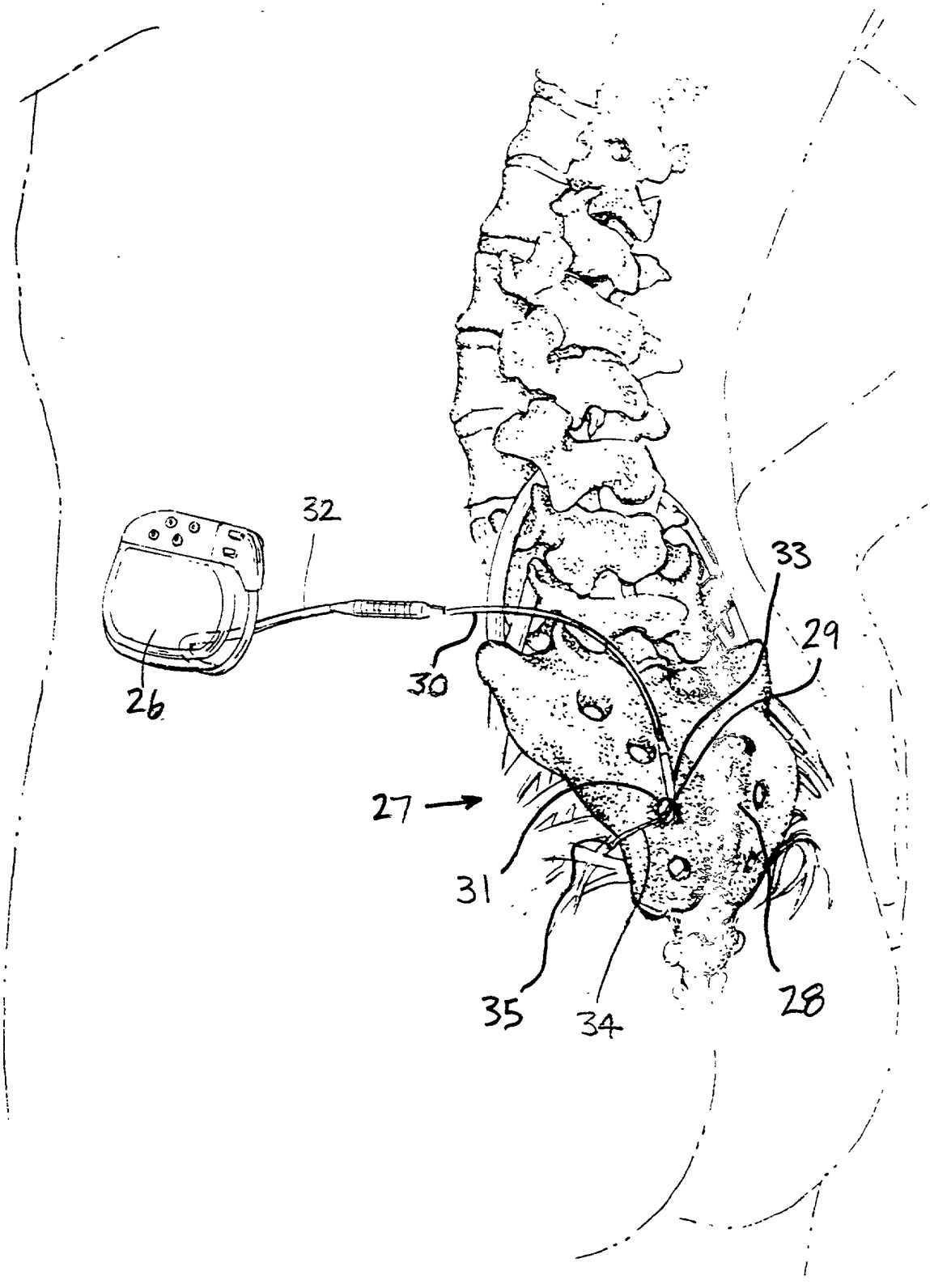


FIG. 1c

FIG 2



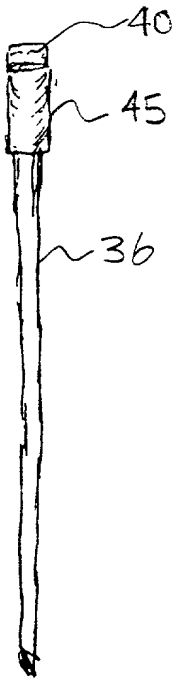


FIG. 3a

FIG. 3b

FIG. 3c

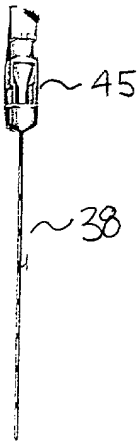


FIG. 3d

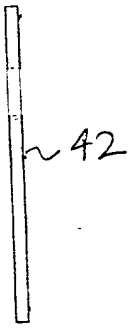


FIG. 3e

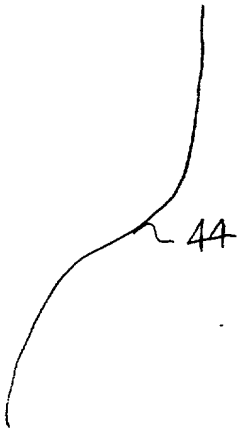


FIG. 3f

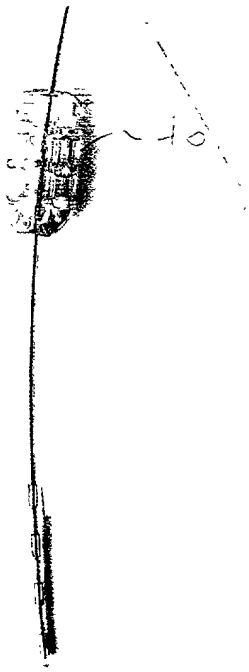


FIG. 3g

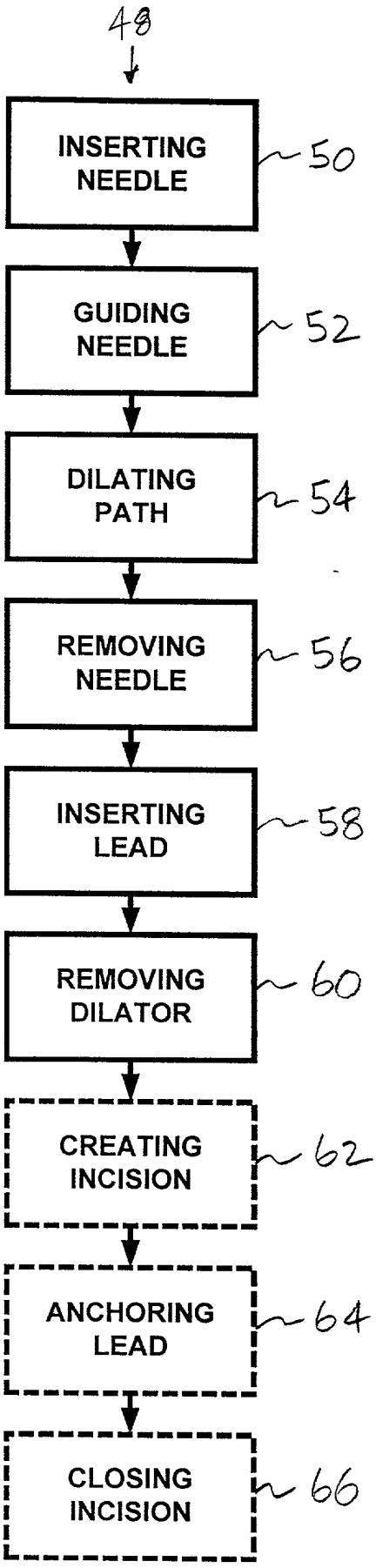

48
INSERTING NEEDLE
50
GUIDING NEEDLE
52
DILATING PATH
54
REMOVING NEEDLE
56
INSERTING LEAD
58
REMOVING DILATOR
60
CREATING INCISION
62
ANCHORING LEAD
64
CLOSING INCISION
66

FIG. 4

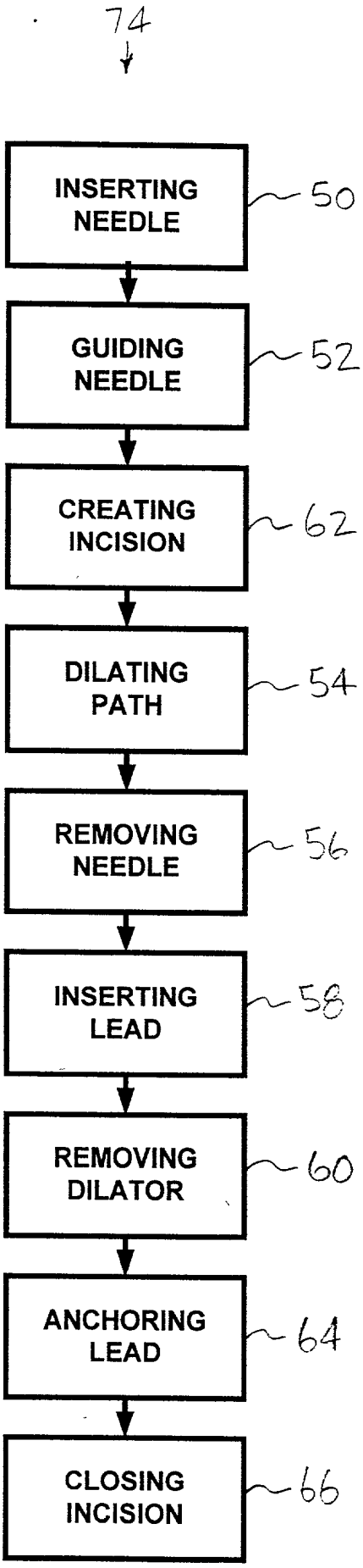

74
INSERTING NEEDLE
50
GUIDING NEEDLE
52
CREATING INCISION
62
DILATING PATH
54
REMOVING NEEDLE
56
INSERTING LEAD
58
REMOVING DILATOR
60
ANCHORING LEAD
64
CLOSING INCISION
66

FIG. 5a

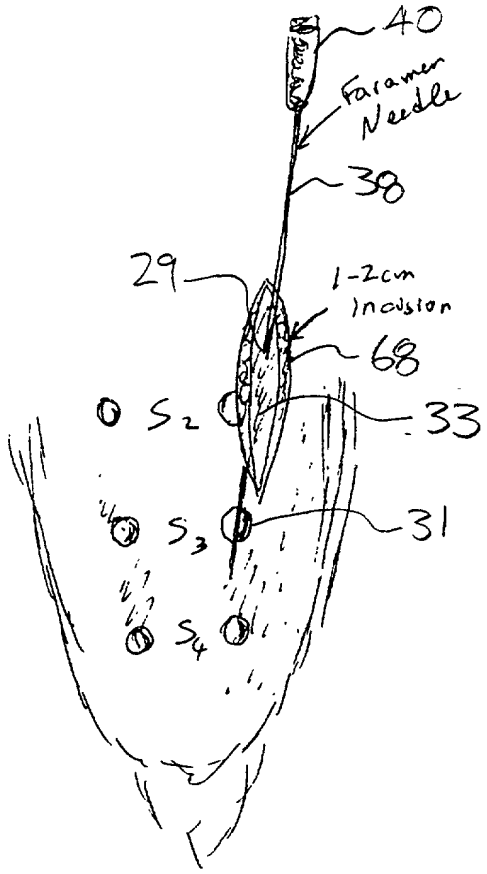

40
Foramen Needle
38
29
1-2cm Incision
68
S_2
33
S_3
31
S_4

FIG. 5b

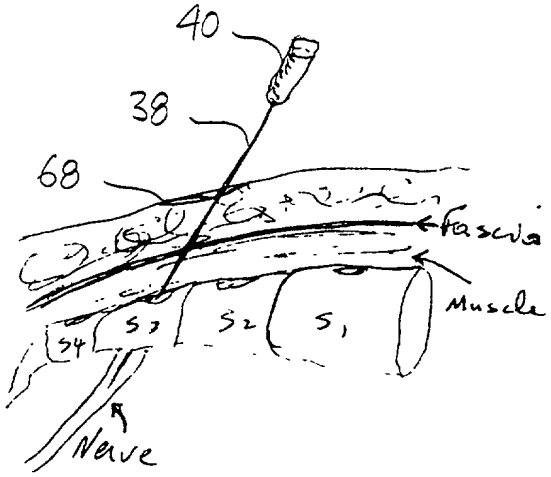

40
38
68
Fascia
Muscle
S4
S3
S2
S1
Nerve

FIG. 5c

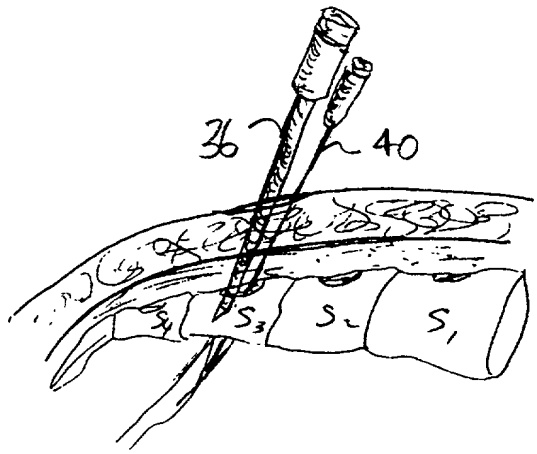


FIG. 5d

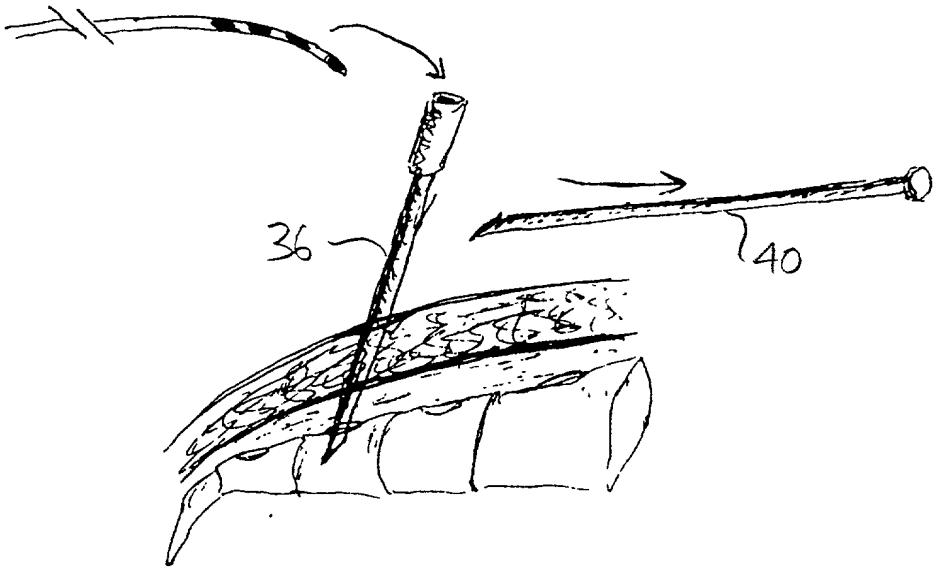


FIG. 5e

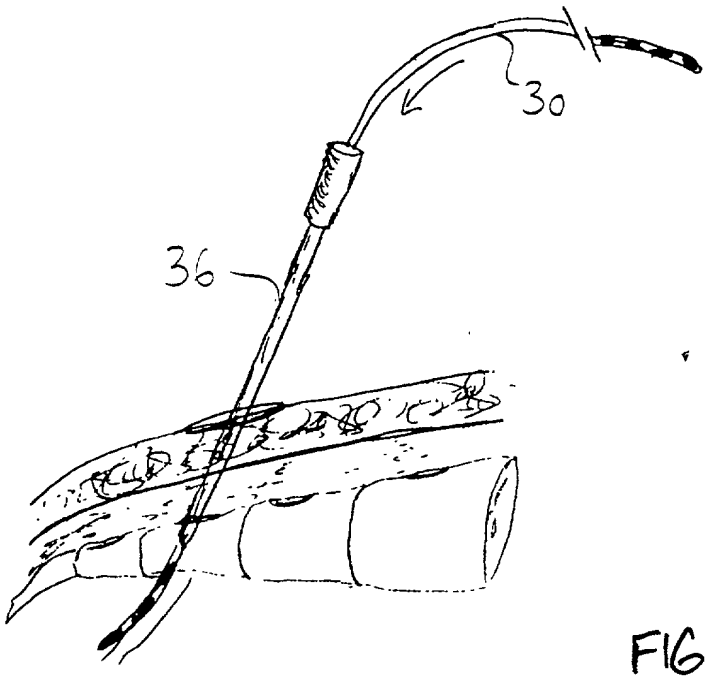


FIG. 5f

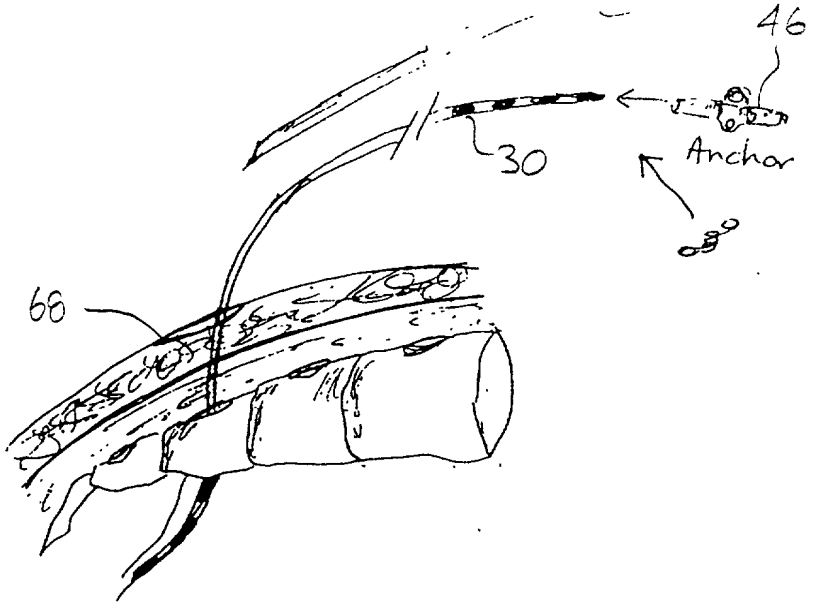


FIG. 5g

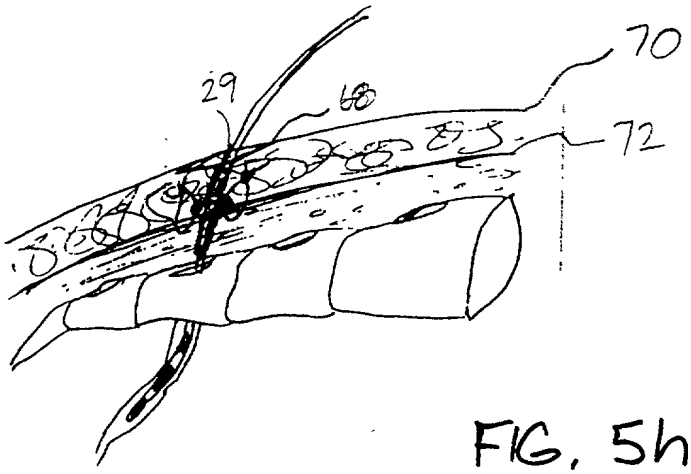

70
29
68
72

FIG. 5h

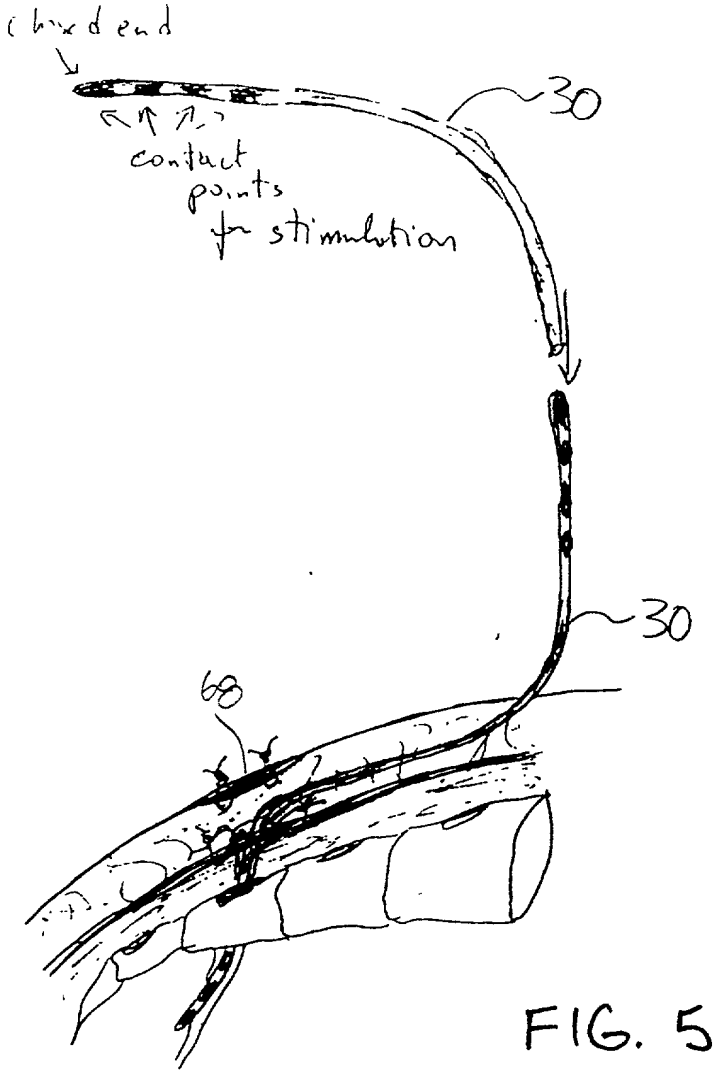

closed end
30
contact points for stimulation
30
68

FIG. 5i

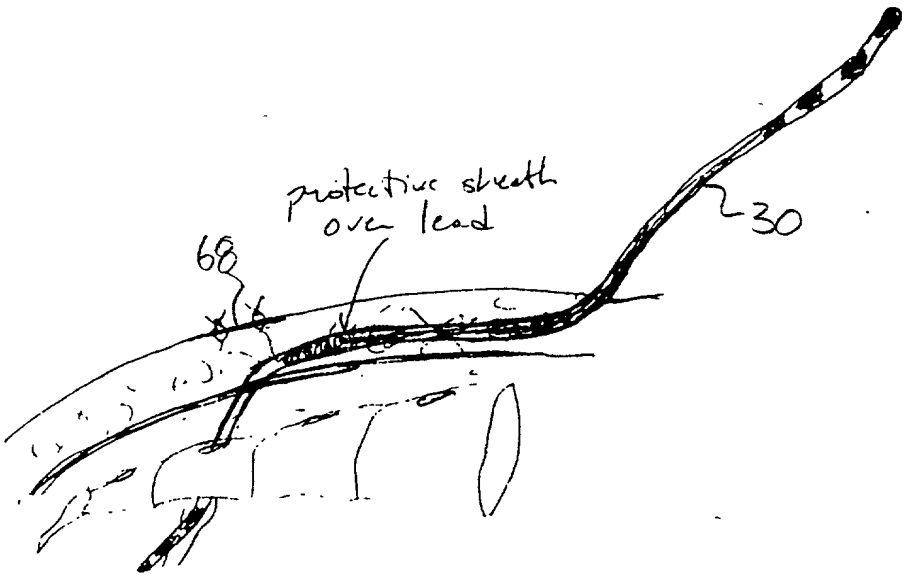

protective sheath
over lead
68
30

FIG. 5j

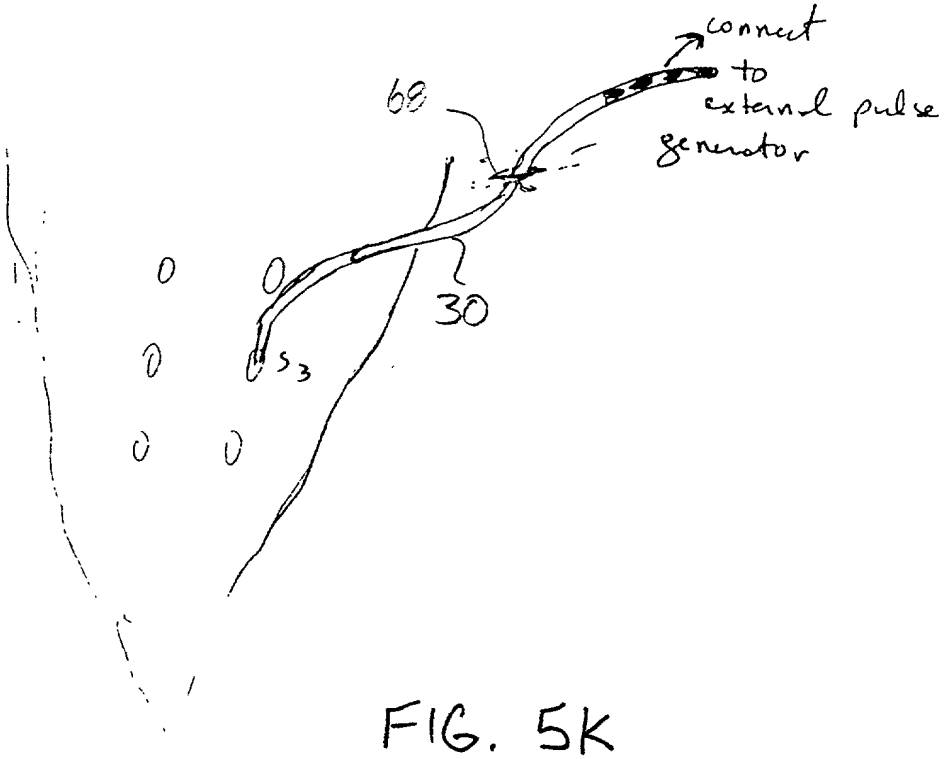

connect
to
external pulse
generator
68
30
S_3

FIG. 5K

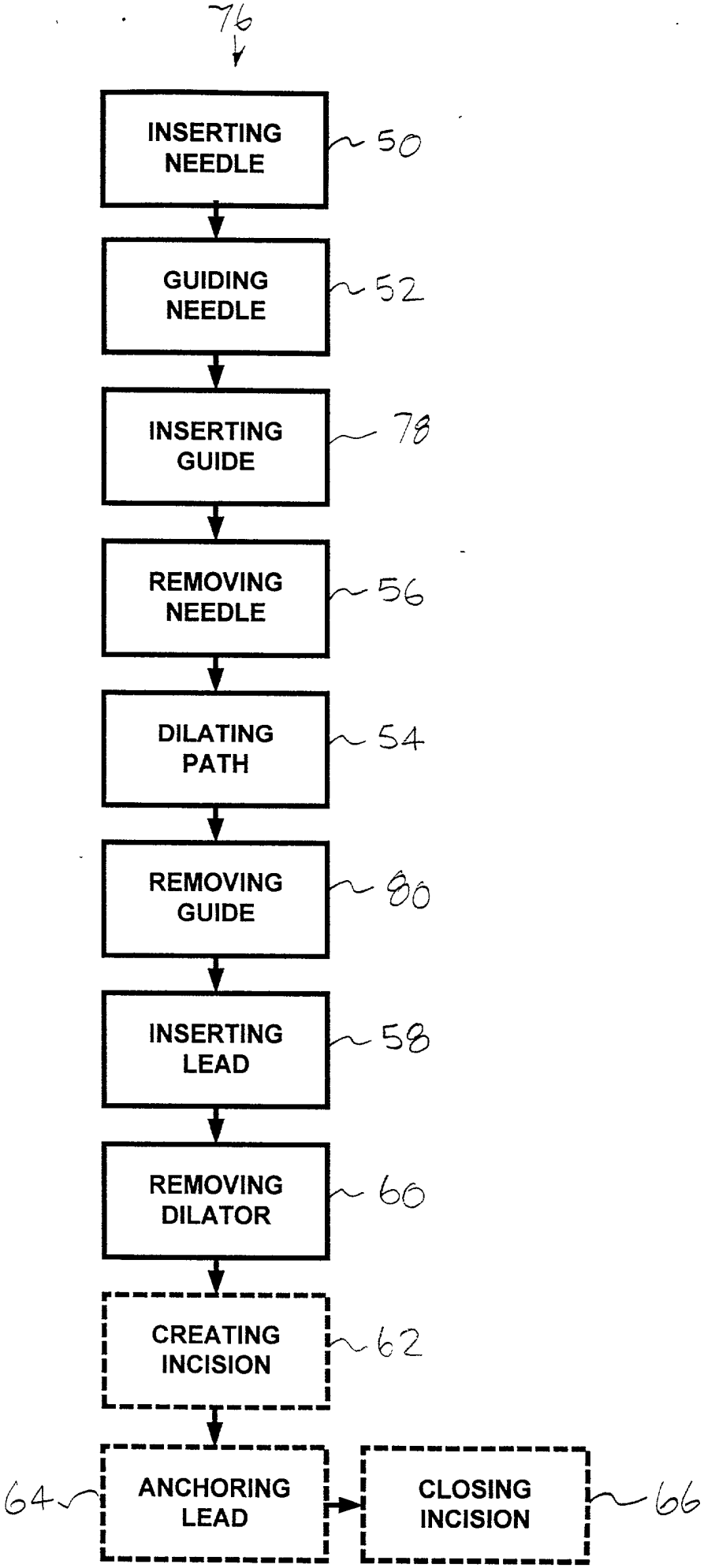

76
INSERTING NEEDLE
50
GUIDING NEEDLE
52
INSERTING GUIDE
78
REMOVING NEEDLE
56
DILATING PATH
54
REMOVING GUIDE
80
INSERTING LEAD
58
REMOVING DILATOR
60
CREATING INCISION
62
64
ANCHORING LEAD
CLOSING INCISION
66

FIG. 6a

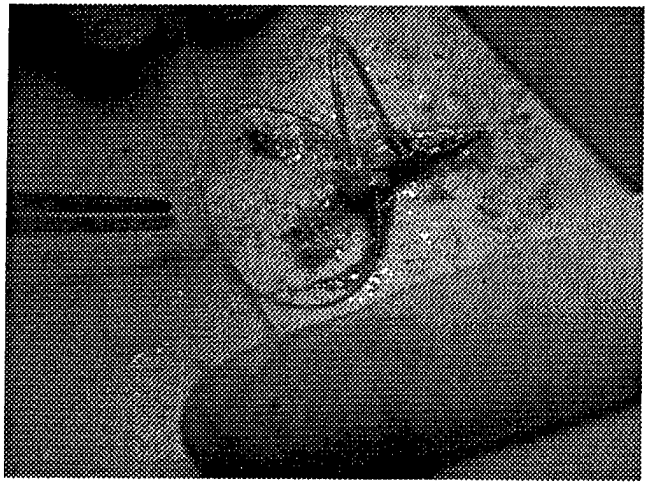


FIG. 6r

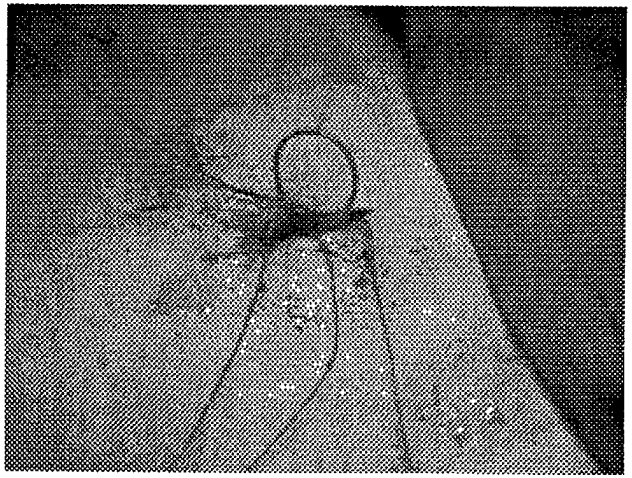


FIG. 6s

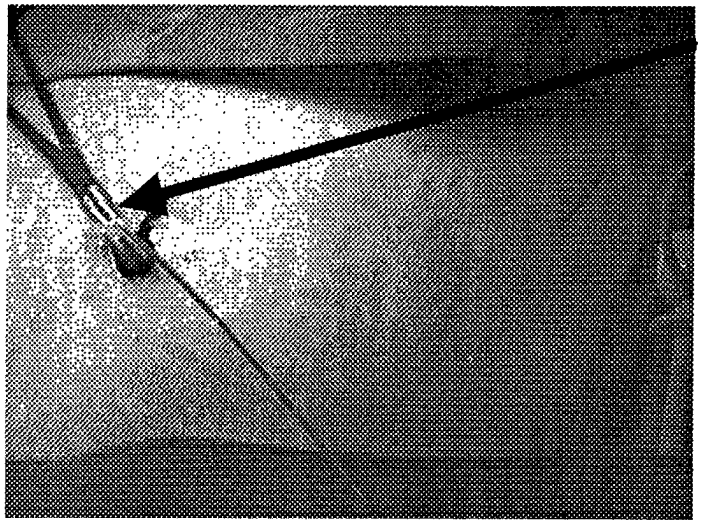


FIG. 6p

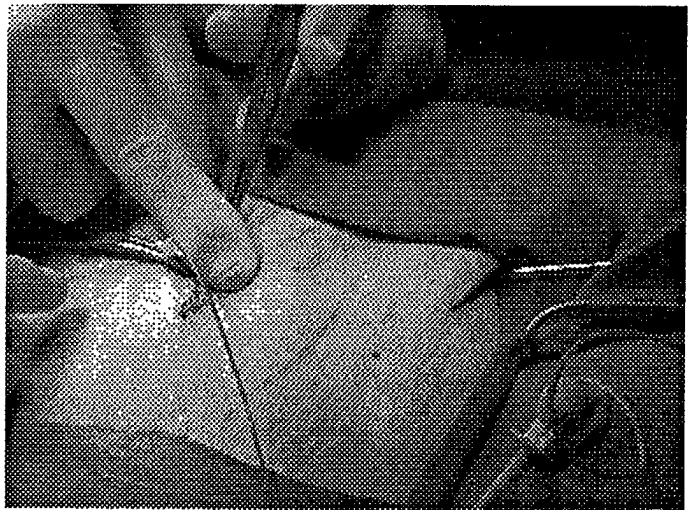


FIG. 6q

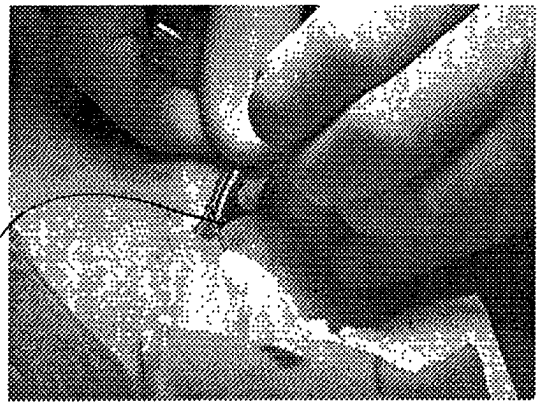


FIG. 6m

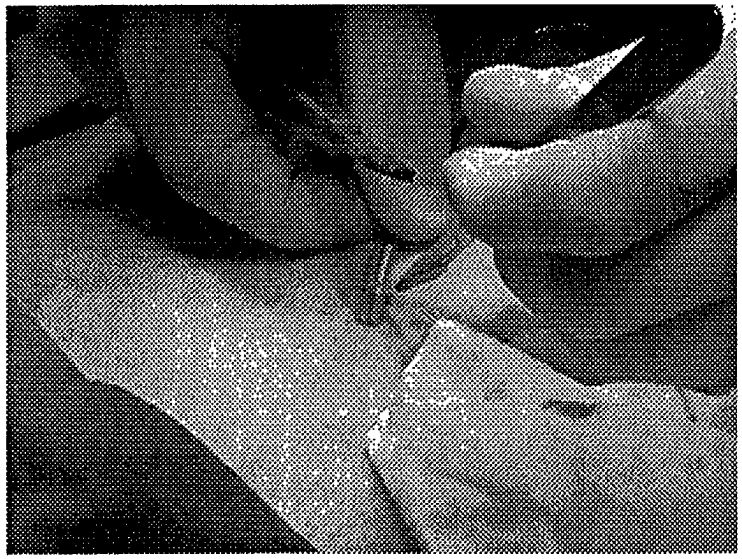


FIG. 6n

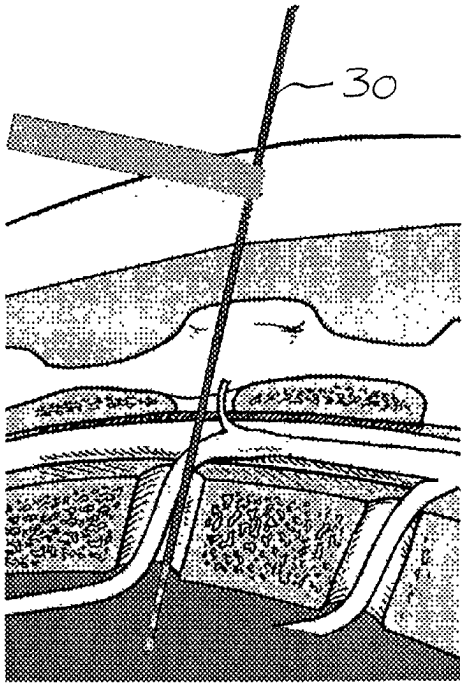


FIG. 6o

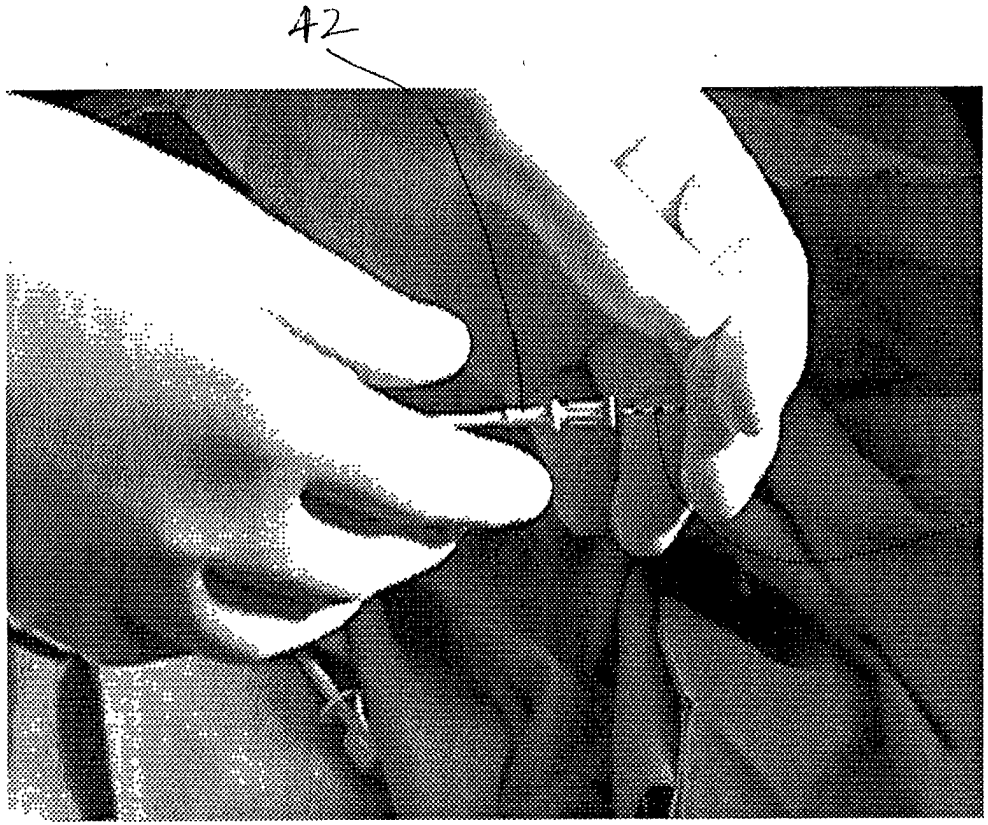


FIG. 61

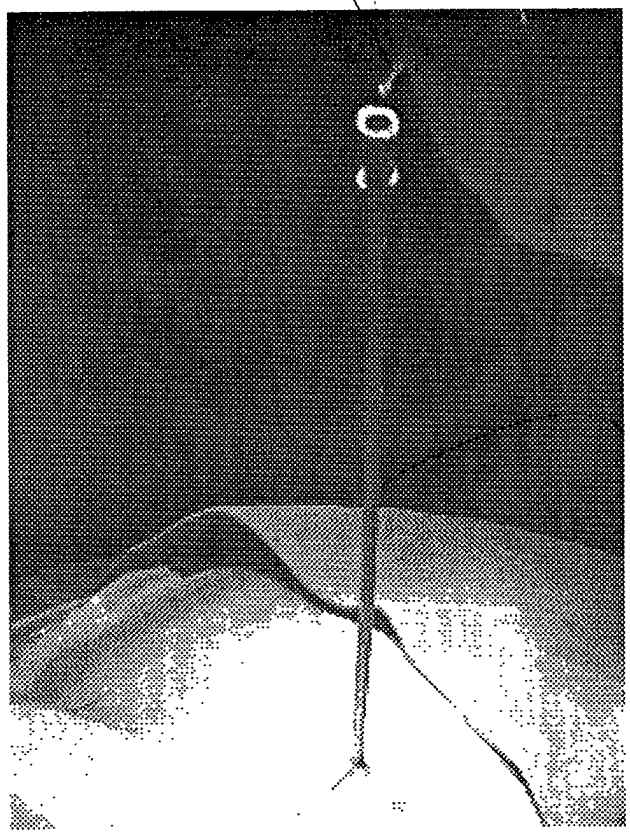


FIG. 6j

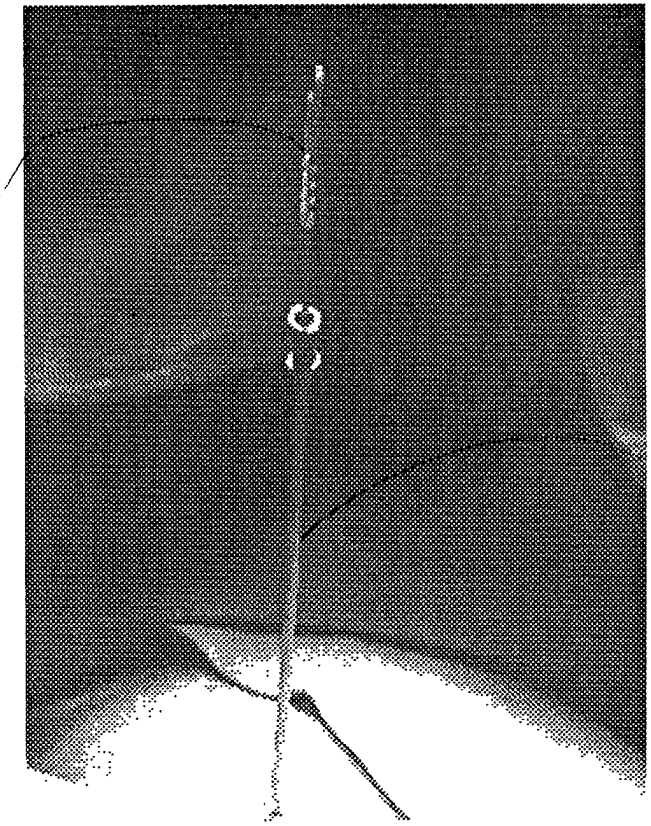


FIG. 6k

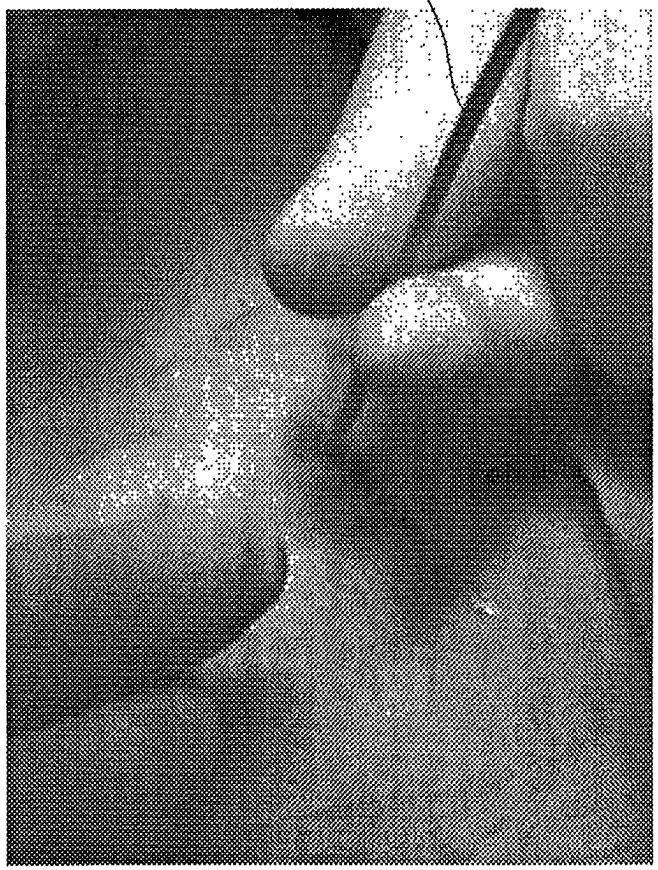


FIG. 6h

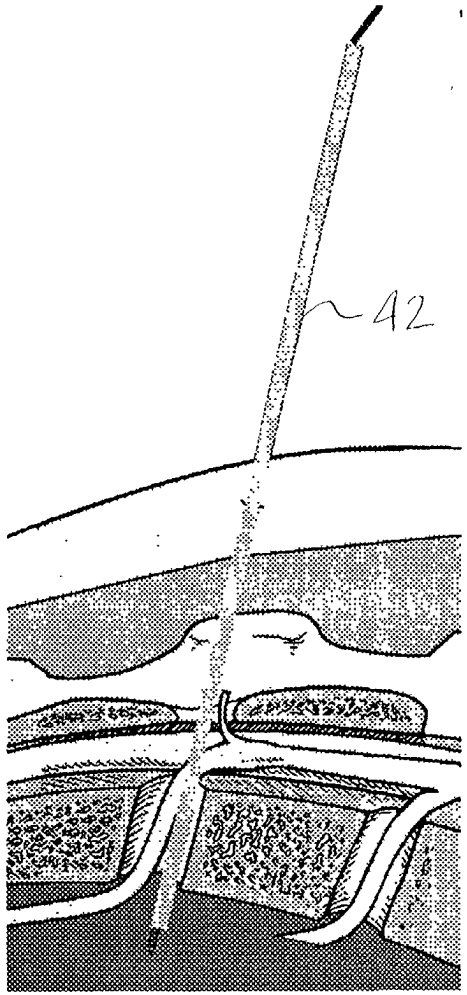


FIG. 6i

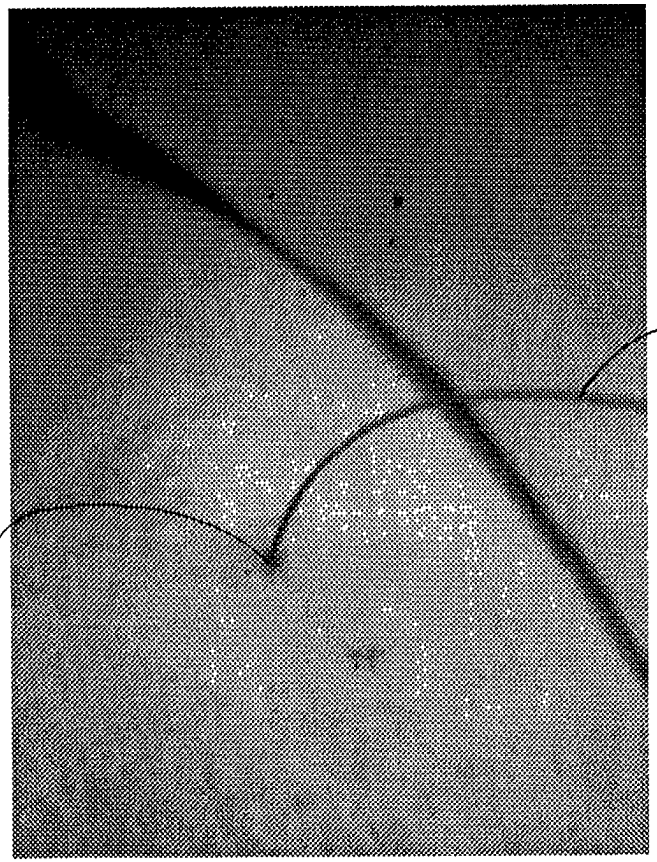


FIG. 6f

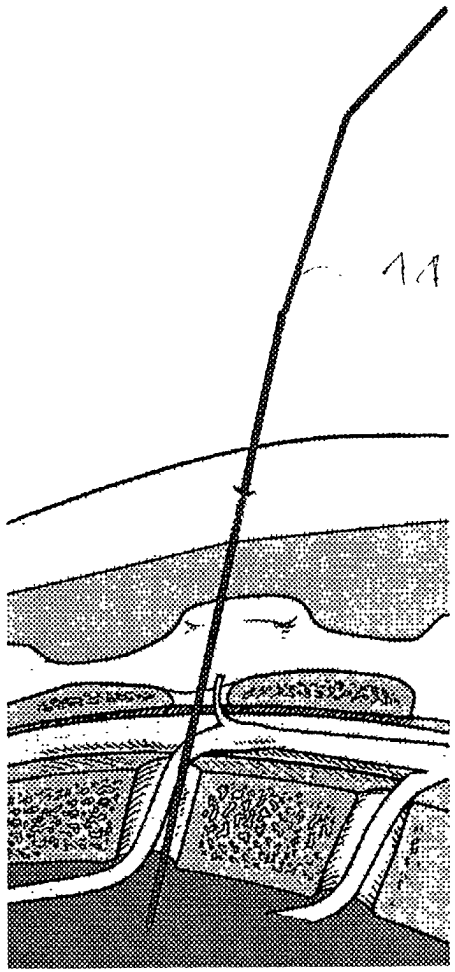


FIG. 6g

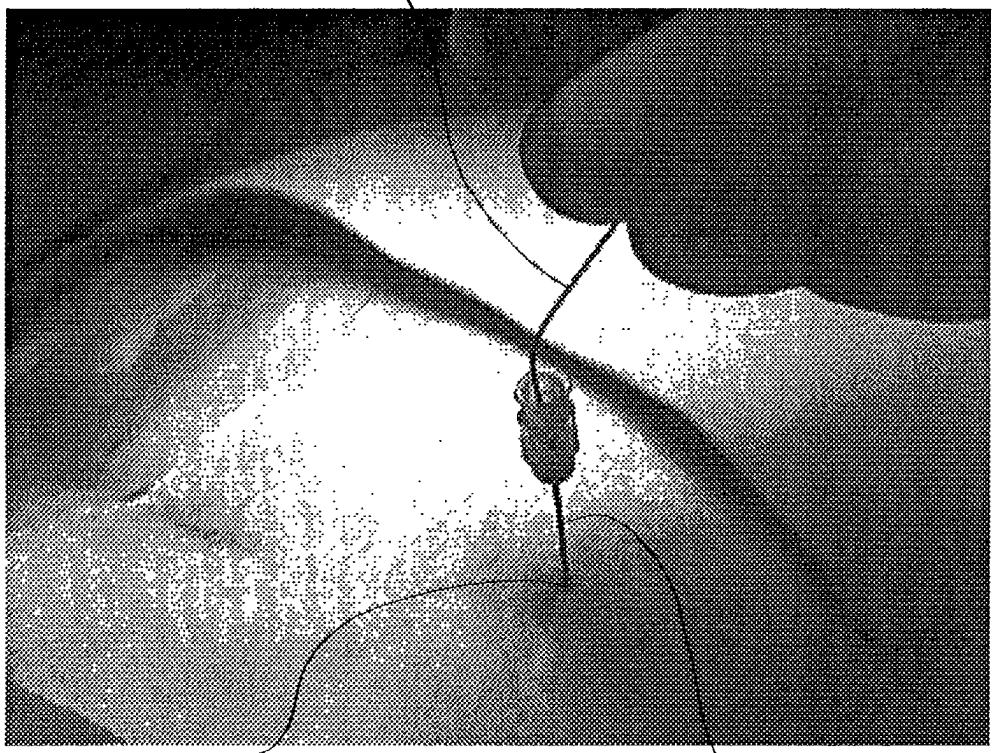


FIG. 6d

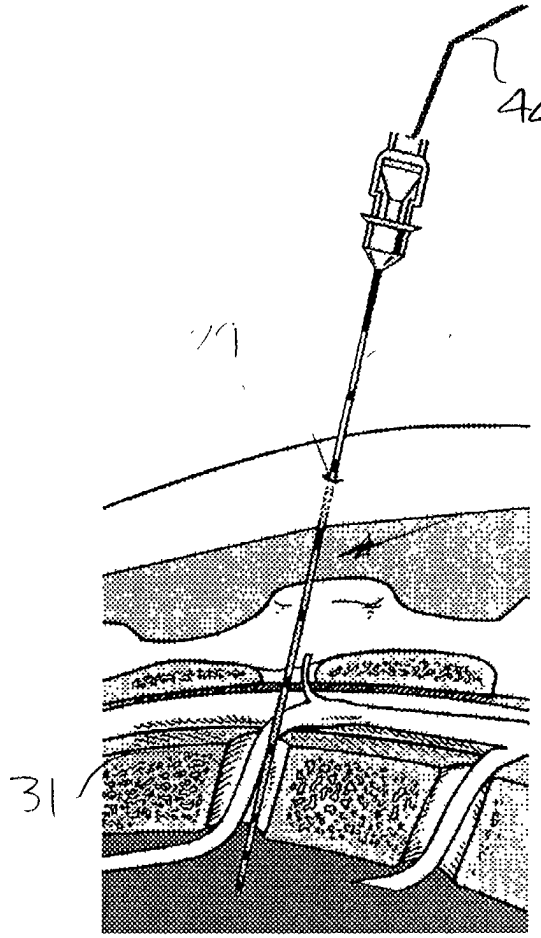


FIG. 6e

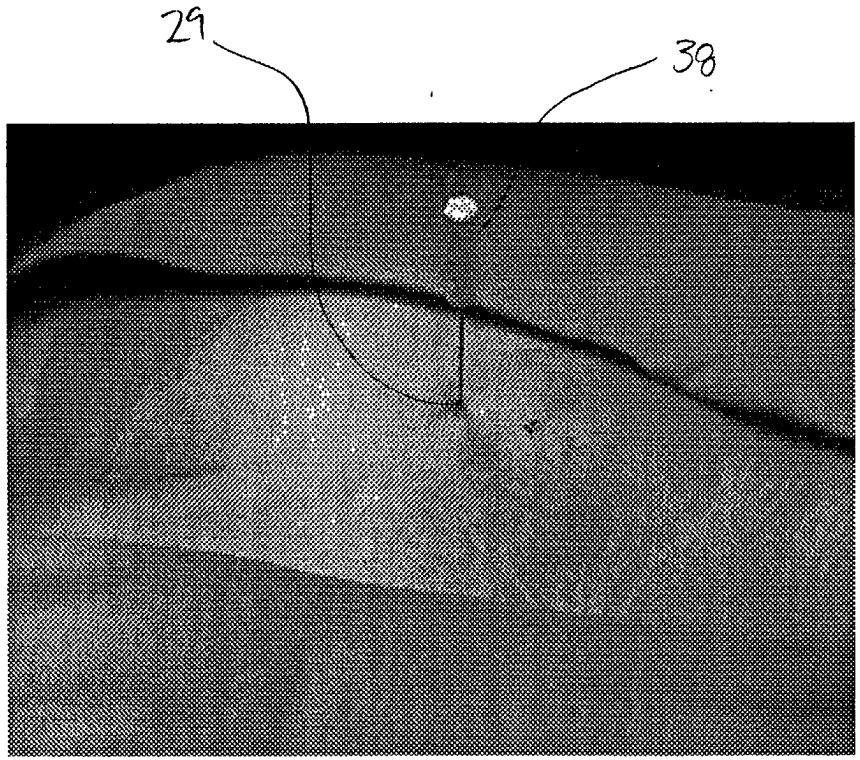


FIG. 6b

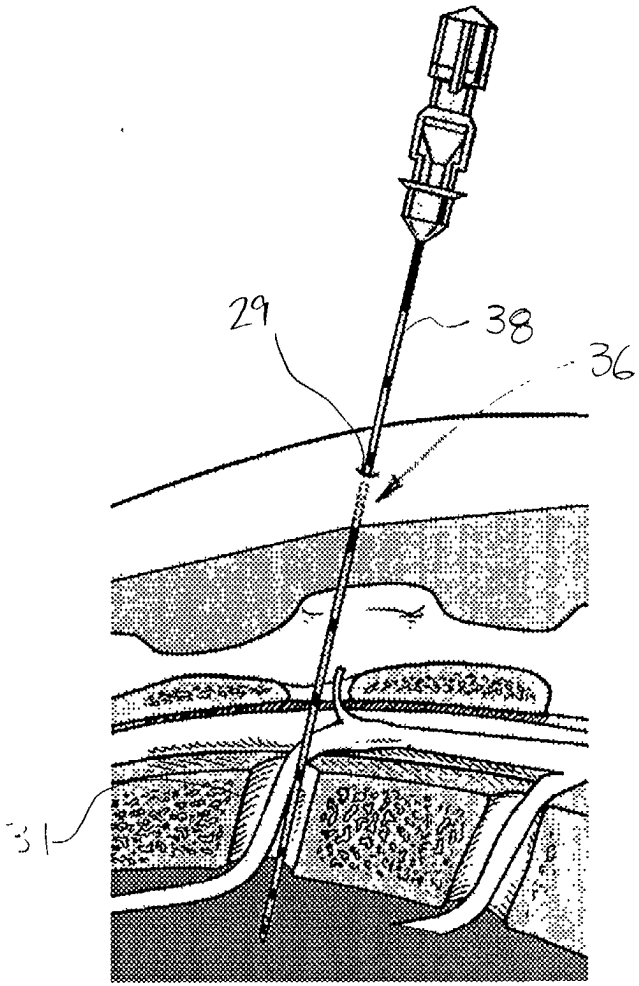


FIG. 6c

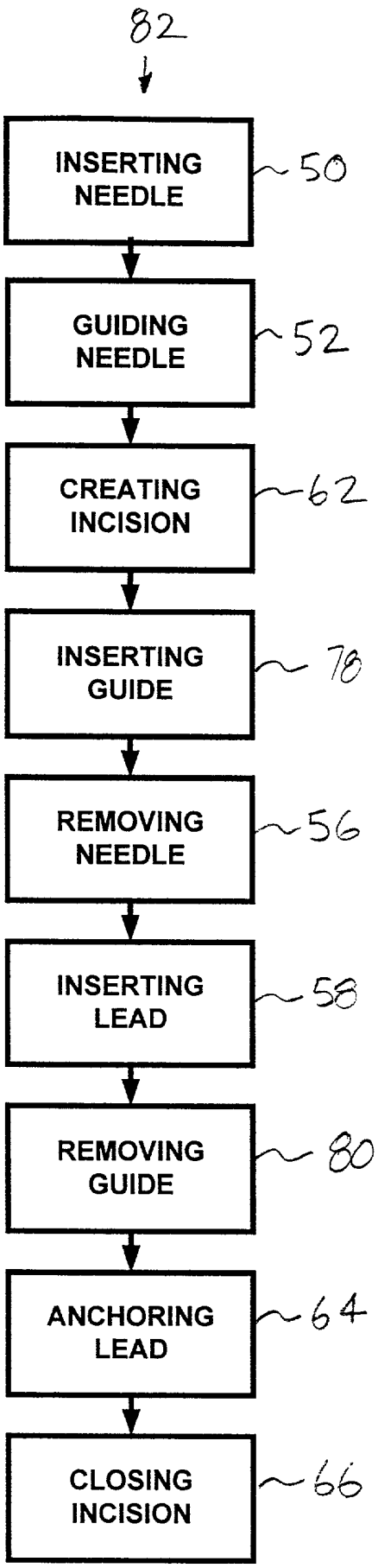

82
INSERTING NEEDLE
50
GUIDING NEEDLE
52
CREATING INCISION
62
INSERTING GUIDE
78
REMOVING NEEDLE
56
INSERTING LEAD
58
REMOVING GUIDE
80
ANCHORING LEAD
64
CLOSING INCISION
66

FIG. 7a

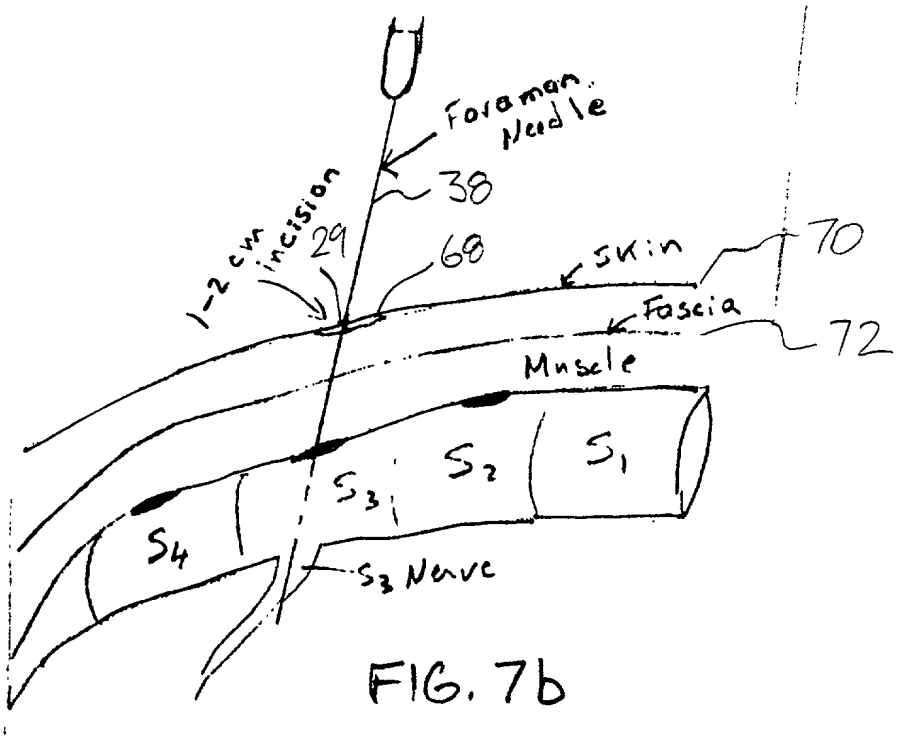

Foraman Needle
38
1-2 cm incision
29
68
Skin
70
Fascia
72
Muscle
S_1
S_2
S_3
S_4
S_3 Nerve

FIG. 7b

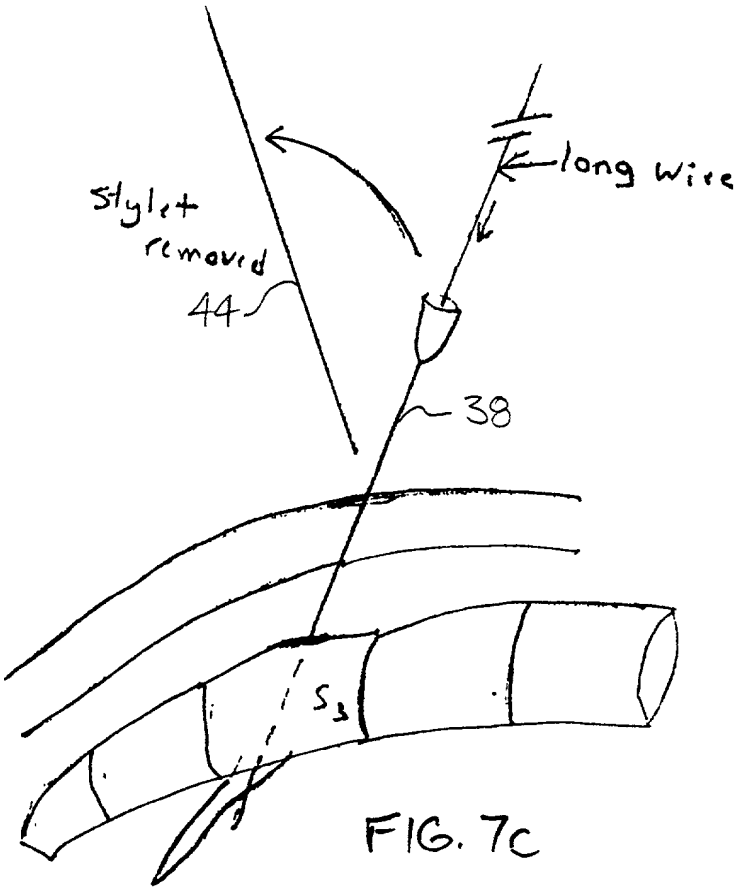

long wire
Stylet removed
44
38
S_3

FIG. 7c

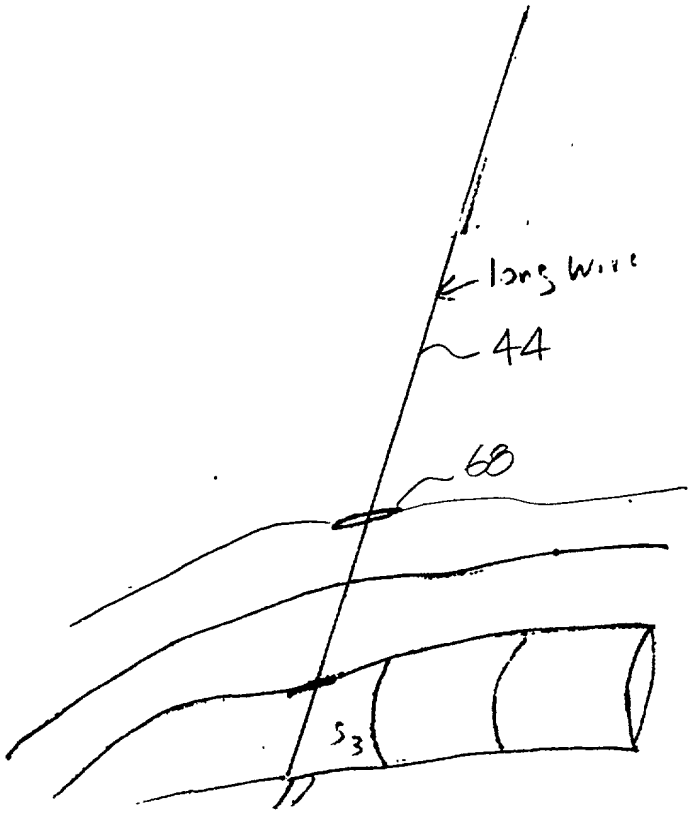


FIG. 7d

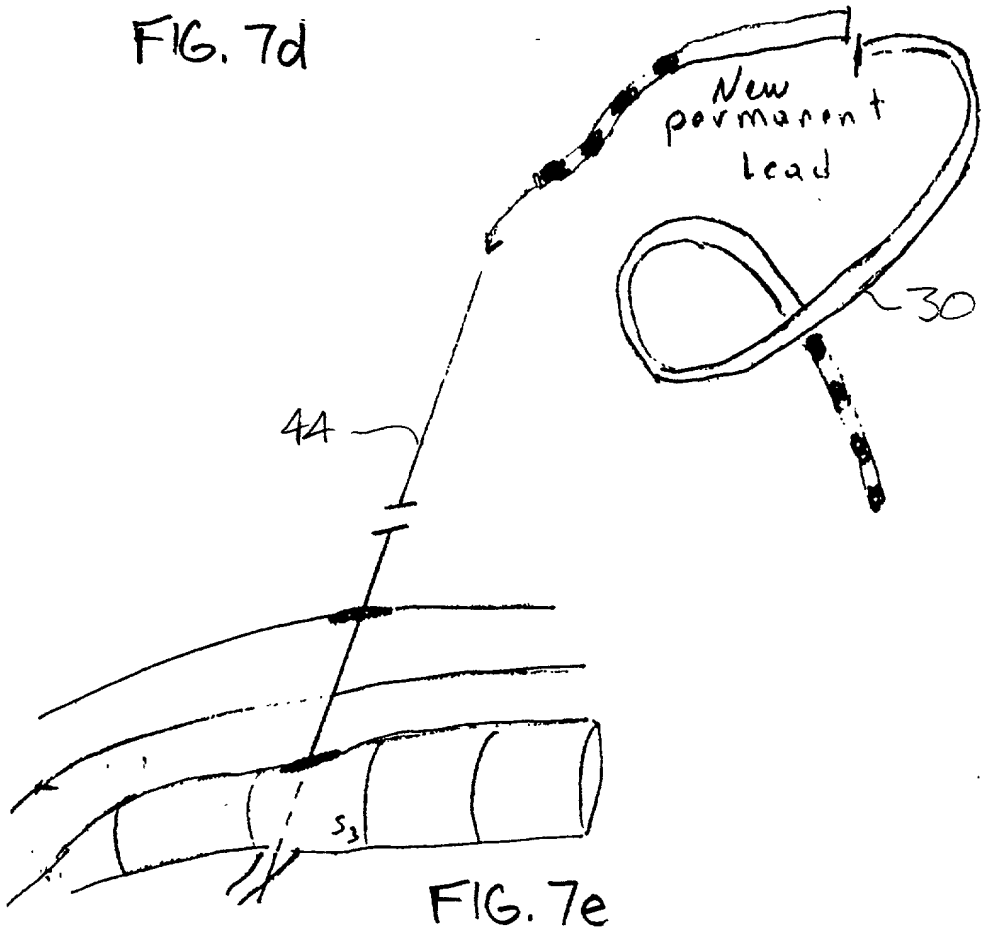


FIG. 7e

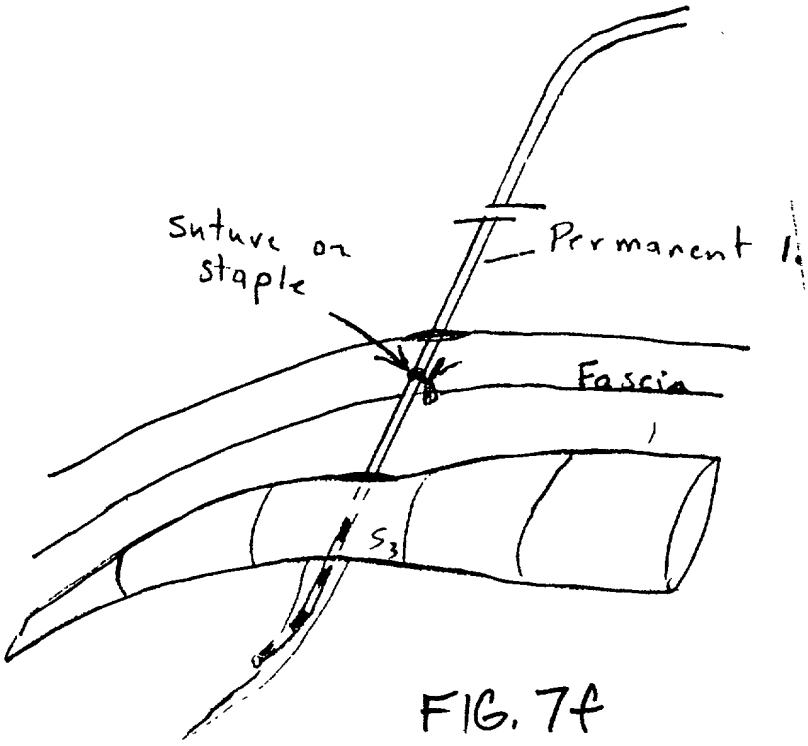


FIG. 7f

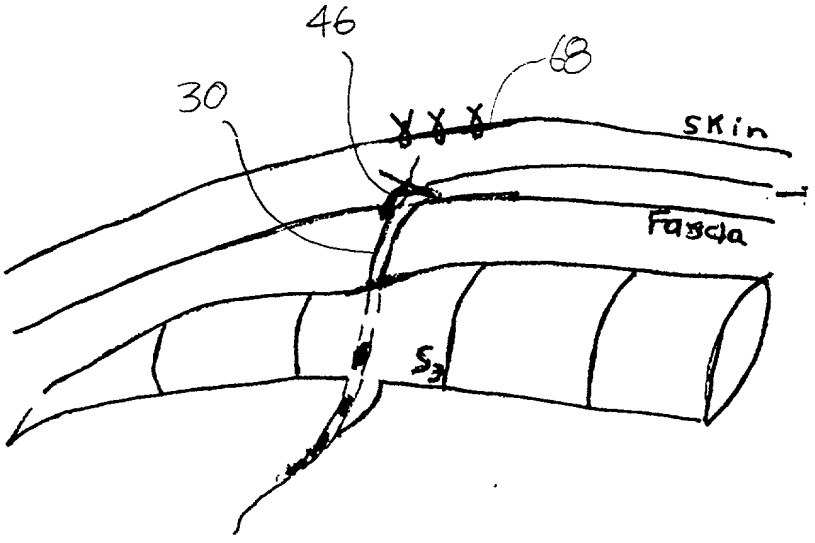


FIG. 7g

ATTORNEY DOCKET: P-9580.00

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **MINIMALLY INVASIVE METHOD FOR IMPLANTING A SACRAL STIMULATION LEAD**

The specification of which
a. X is attached hereto
b. ____ was filed on ___ as application serial no. __ and was amended on ____ (if applicable) (in the case of a PCT-filed application) described and claimed in international no. ___ filed ___ and as amended on ____ (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).[1]

I hereby claim foreign priority benefits under Title 35, United States Code, §119/365 of any foreign application(s) for patent of inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed.

a. x no such applications have been filed.
b. ... such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC §119

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

ALL FOREIGN APPLICATIONS, IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

I hereby claim the benefit under Title 35, United States Code, §120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §156(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

[1] **§ 1.56 Duty of disclosure; fraud, striking or rejection of applications.**

(a) A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.

U.S. APPLICATION NUMBER	DATE OF FILING	STATUS (patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Harold R. Patton	Reg. No. 22,157	Beth L. McMahon	Reg. No. 41,987	Kenneth J. Collier	Reg. No. 34,982
Michael J. Jaro	Reg. No. 34,472	Daniel W. Latham	Reg. No. 30,401	Thomas G. Berry	Reg. No. 31,736
Girma Wolde-Michael	Reg. No. 36,724	Curtis D. Kinghorn	Reg. No. 33,926		
Thomas F. Woods	Reg. No. 36,726	Eric R. Waldkoetter	Reg. No. 36,713		

Please direct all correspondence in this case to. Medtronic, Inc.
7000 Central Avenue N.E.
Minneapolis, Minnesota 55432
Telephone No. (763) 514-3346

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

201	Full Name of Inventor	FIRST NAME George	MIDDLE INITIAL	LAST NAME Mamo
	Residence & Citizenship	CITY Ellicott City	STATE OR FOREIGN COUNTRY Maryland	CITIZENSHIP US
	Post Office Address	POST OFFICE ADDRESS 5109 Morningside Lane	CITY Ellicott City	STATE/ZIP/COUNTRY Maryland 21043 US
SIGNATURE OF INVENTOR 201				DATE 11/10/00
202	Full Name of Inventor	FIRST NAME Michele	MIDLE INITIAL	LAST NAME Spinelli
	Residence & Citizenship	CITY 20136 Milano	STATE OR FOREIGN COUNTRY ITALY	CITIZENSHIP Italian
	Post Office Address	POST OFFICE ADDRESS Via Vittadina 21	CITY 20136 Milano	STATE/ZIP/COUNTRY Italy 20136
SIGNATURE OF INVENTOR 202				DATE
203	Full Name of Inventor	FIRST NAME	MIDDLE INITIAL	LAST NAME
	Residence & Citizenship	CITY	STATE OR FOREIGN COUNTRY	CITIZENSHIP
	Post Office Address	POST OFFICE ADDRESS	CITY	STATE/ZIP/COUNTRY
SIGNATURE OF INVENTOR 203				DATE

__ Additional pages for fourth and subsequent inventors attached

_X_ This Declaration ends with this page.

Medtronic Italia S.p.A.
Viale Fulvio Testi, 280
20126 Milano
Tel. 0266164.1 (45 linee r.a.)
Fax 026427488

ATTORNEY **Medtronic**

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **MINIMALLY INVASIVE METHOD FOR IMPLANTING A SACRAL STIMULATION LEAD**

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a. X is attached hereto
b. _____ was filed on _____as application serial no. _____ and was amended on _____ (if applicable) (in the case of a PCT-filed application) described and claimed in international no _____ filed _____ and as amended on _____ (if any), which I have reviewed and for which I solicit a United States patent

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a. X no such applications have been filed.
b. _ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC §119

COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

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COUNTRY	APPLICATION NUMBER	DATE OF FILING	DATE OF ISSUE

I hereby claim the benefit under Title 35, United States Code, §1120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §156(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

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Medtronic

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Girma Wolde-Michael	Reg. No. 36,724	Curtis D. Kinghorn	Reg. No. 33,926		
Thomas F Woods	Reg. No. 36,726	Eric R. Waldkoetter	Reg. No. 36,713		

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Minneapolis, Minnesota 55432
Telephone No. (763) 514-3346

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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	Post Office Address	POST OFFICE ADDRESS 5109 Morningside Lane	CITY Ellicott City	STATE/ZIP/COUNTRY Maryland 21043 US
SIGNATURE OF INVENTOR 201				DATE

202	Full Name of Inventor	FIRST NAME Michele	MIDLE INITIAL	LAST NAME Spinelli
	Residence & Citizenship	CITY 20136 Milano	STATE OR FOREIGN COUNTRY ITALY	CITIZENSHIP Italian
	Post Office Address	POST OFFICE ADDRESS Via Vittadini 21	CITY 20136 Milano	STATE/ZIP/COUNTRY Italy 20136
SIGNATURE OF INVENTOR 202				DATE

203	Full Name of Inventor	FIRST NAME	MIDDLE INITIAL	LAST NAME
	Residence & Citizenship	CITY	STATE OR FOREIGN COUNTRY	CITIZENSHIP
	Post Office Address	POST OFFICE ADDRESS	CITY	STATE/ZIP/COUNTRY
SIGNATURE OF INVENTOR 203				DATE

__ Additional pages for fourth and subsequent inventors attached.

X This Declaration ends with this page.